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Guidance for the Reregistration of Pesticide Products Containing Azinphos Methyl as the Active Ingredient

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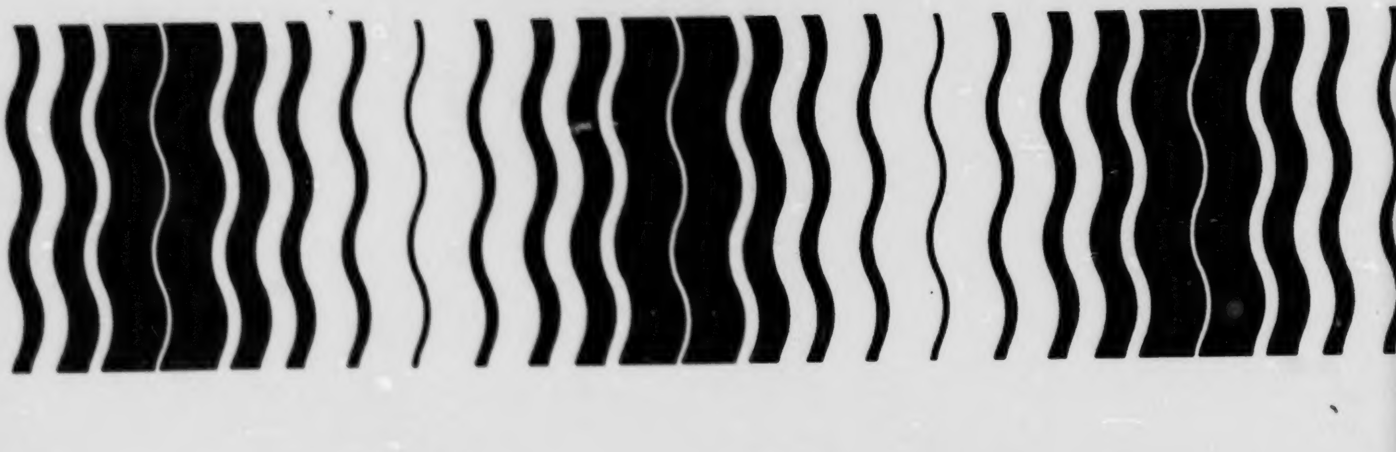
Guidance for the Reregistration of Pesticide Products Containing Azinphos-Methyl as the Active Ingredient



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This document contains information regarding the reregistration of pesticide products containing the subject active ingredient. The document includes how to register under a registration standard, regulatory position and rationale, and summaries of data requirements and data gaps. Also included is a bibliography containing citations of all studies reviewed by EPA in arriving at the positions and conclusions contained in the standard.

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GUIDANCE FOR THE REREGISTRATION OF PESTICIDE PRODUCTS

CONTAINING

AZINPHOS-METHYL

AS THE ACTIVE INGREDIENT

EPA CASE NUMBER 235

ENVIRONMENTAL PROTECTION AGENCY

OFFICE OF PESTICIDE PROGRAMS

WASHINGTON, D.C. 20460

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APPENDICES

I. DATA APPENDICES

Guide to Tables

Table A

Table B

Table C

II. LABELING APPENDICES

Summary of label requirements and table

40 CFR 162.10 Labeling Requirements

Physical/Chemical Hazards Labeling Statements

Storage Instructions

Pesticide Disposal Instructions

Container Disposal Instructions

III. USE INDEX APPENDIX

IV. BIBLIOGRAPHY APPENDICES

Guide to Bibliography

Bibliography

V. FORMS APPENDICES

EPA Form 8580-1	FIFRA §3(c)(2)(B) Summary Sheet
EPA Form 8580-6	Certification of Attempt to Enter Into an Agreement with Other Registrants for Development of Data
EPA Form 8580-4	Product Specific Data Report
EPA Form 8570-27	Formulator's Exemption Statement

TABLE OF CONTENTS

I. Introduction P.1

II. Chemical(s) Covered by this Standard P.4
- A. Description of Chemical
- B. Use Profile

III. Agency Assessment P.7
- A. Summary
- B. Preliminary Risk Assessment
- C. Other Science Findings
- D. Tolerance Reassessment

IV. Regulatory Position and Rationale. P.30
- A. Regulatory Positions
- B. Criteria for Registration
- C. Acceptable Ranges and Limits
- D. Required Labeling

V. Products Subject to this Standard P.56

VI. Requirement for Submission of Generic Data P.58
- A. What are generic data?
- B. Who must submit generic data?
- C. What generic data must be submitted?
- D. How to comply with DCI requirements
- E. Procedures for requesting a change in protocol
- F. Procedures for requesting extensions of time
- G. Existing stocks provisions upon suspension or cancellation

VII. Requirement for Submission of Product-Specific Data P.63

VIII. Requirement for Submission of Revised Labeling . . P.64

IX. Instructions for Submission. P.65
- A. Manufacturing use products (sole active)
- B. Manufacturing use products (multiple active)
- C. End use products
- D. Intrastate products
- E. Addresses

I. INTRODUCTION

The Registration Standards Program

EPA has established the Registration Standards program in order to provide an orderly mechanism by which pesticide products containing the same active ingredient can be reviewed and standards set for compliance with FIFRA. The standards are applicable to reregistration and future applications for registration of products containing the same active ingredient.

Each registrant of a product containing the active ingredient subject to this Standard who wishes to continue to sell or distribute that product must bring his product and labeling into compliance with FIFRA, as instructed by this Standard. Pesticides have been grouped into use clusters and will be reviewed on the basis of a ranking scheme giving higher priority to (1) pesticides in clusters used on food and feed crops; and (2) pesticides produced in large volumes.

The Registration Standards program involves a thorough review of the scientific data base underlying a pesticide's registration. The purpose of the Agency's review is to reassess the potential hazards arising from the currently registered uses of the pesticide; to determine the need for additional data on health and environmental effects; and to determine whether the pesticide meets the "no unreasonable adverse effects" criteria of FIFRA.

In its review EPA identifies:

1. Studies that are acceptable to support the data requirements for the currently registered uses of the pesticide.

2. Additional studies necessary to support continued registration. The additional studies may not have been required when the product was initially registered or may be needed to replace studies that are now considered inadequate.

3. Labeling revisions needed to ensure that the product is not misbranded and that the labeling is adequate to protect man and the environment.

The detailed scientific review, which is not contained in this document, but is available upon request[1], focuses on the pesticide active ingredient. The scientific review primarily discusses the Agency's evaluation of and conclusions from available data in its files pertaining to the pesticide active ingredient. However, during the review of these data, the Agency is also looking for potential hazards that may be associated with the end use products that contain the active ingredient. The Agency will apply the provisions of this Registration Standard to end use products if necessary to protect man and the environment.

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[1] The scientific reviews are available upon request from the Information Services Section, Room 236, CM# 2, 1921 Jefferson Davis Highway, Arlington, Va., 22202 (703-557-4453). Ninety days after the issuance of the standard, the reviews may be purchased from the Technical Information Service, 5285 Port Royal Road, Springifeld, Va., 22161.

EPA's reassessment results in the development of a regulatory position, contained in this Registration Standard, on the pesticide and each of its registered uses. See Section IV - Regulatory Position and Rationale. Based on its regulatory position, the Agency may prescribe a variety of steps to be taken by registrants to maintain their registrations in compliance with FIFRA. These steps may include:

1. Submission of data in support of product registration;
2. Modification of product labels;
3. Modifications to the manufacturing process of the pesticide to reduce the levels of impurities or contaminants;
4. Restriction of the use of the pesticide to certified applicators or other specially trained individuals;
5. Modification of uses or formulation types; or
6. Specification of packaging limitations.

Failure to comply with these requirements may result in the issuance of a Notice of Intent to Cancel or a Notice of Intent to Suspend (in the case of failure to submit data).

In addition, in cases in which hazards to man or the environment are identified, the Agency may initiate a special review of the pesticide in accordance with 40 CFR Part 154 to examine in depth the risks and benefits of use of the pesticide. If the Agency determines that the risks of the pesticide's use outweigh the benefits of use, the Agency may propose additional regulatory actions, such as proposed cancellation of uses of the pesticide which have been determined to cause unreasonable adverse effects on the environment. EPA has authority under the Data Call-In (DCI) provisions of FIFRA sec. 3(c)(2)(B) to require that registrants submit data to answer our questions regarding the chemical, toxicological and environmental characteristics and fate of a pesticide. This Registration Standard lists the data EPA believes are necessary to resolve our concerns about this pesticide. These data are listed in Section V - Requirement for Submission of Generic Data, and Section VI - Requirement for Submission of Product-Specific data. Failure to comply with the DCI requirements enumerated in this Registration Standard may result in issuance by EPA of a Notice of Intent to Suspend the affected product registrations.

Registrants are reminded that FIFRA sec. 6(a)(2) requires them to submit factual information concerning possible unreasonable adverse effects of a pesticide at any time that they become aware of such information. You shall notify the Agency of any information, including interim or preliminary results of studies, if those results suggest possible adverse effects on man or the environment. This requirement continues as long as your products are registered by the Agency.

II. CHEMICAL COVERED BY THIS STANDARD

A. Description of Chemical

The following chemical is covered by this Registration Standard:

Common name: Azinphos-methyl
Chemical name: O,O-dimethyl-S-[(4-oxo-1,2,3-benzotriazin-3(4H)-yl)methyl] phosphordithioate
Chemical class: Organophosphate
CAS Number: 86-50-0
OPP (Shaughnessy) Number: 058001
Empirical Formula: $C_{10}H_{12}N_3PS_2$

Trade names: metiltrizotion, carfene, cotion, cotion-methyl, gusathion, gusathion-M, guthion, Bay 9027, Bay 17147, R-1582 and chrysthyon

Description of physical characteristics of chemical:

Technical Azinphos-methyl
Color: Yellow-Brown
Physical State: Waxy solid
Melting Point: 60-63°C
Solubility: soluble in wide range of organic solvents, insoluble in water
Boiling Point: decomposes
Specific gravity: 1.44 at 20°C
Vapor Pressure: 2.2×10^{-7}mm Hg at 20°C
Molecular Weight: 317.1

Predominant Uses: Cotton, Apples and Peaches

Types of Pesticide: Insecticide, Acaricide and Molluscicide

Mode of Activity: Cholinesterase Inhibition

Pest Controlled: More than 200 Agricultural Pests (Refer to Appendix III. for Pesticide Index)

B. Use Profile

Azinphos-methyl is a broad spectrum organophosphate insecticide, acaricide and molluscicide that has been marketed in the U.S. for over 25 years. Azinphos-methyl was first registered by Mobay Chemical Corporation in 1959. Technical azinphos-methyl is produced by Bayer AG (Federal Republic of Germany), Makhteshim Chemical Works (Israel), and in the United States by Mobay Chemical Corporation and Aceto Chemical Company. Approximately 3 million pounds active ingredient are used annually for control of more than 200 pests on about 50 sites. There are approximately 125 single active ingredients and 19 multiple active ingredient products registered including the following formulation types:

Technical	(85%, 94%)
Formulation Intermediate	(1lb/gal, 21%, 22%, 25%)

Dust	(2%, 2.5%, 3%, 6%)
Granular	(5%, 7%, 10%)
Wettable Powder	(25%, 50%, 62.5%)
Emulsifiable Concentrate	(0.25 lb/gal, 0.75 lb/gal, 1 lb/gal, 1.5 lb/gal, 2 lb/gal, 5%, 12.37%)
Flowable Concentrate	(2 lb/gal, 3 lb/gal)
Soluble Concentrate	(12.4%)

(Liquid formulations containing greater than 13.5% active ingredient are classified as restricted use pesticides).

Methods of Application include:

Foliar spray or dust by air or ground equipment
Soil broadcast preplant or at planting
Soil broadcast (in established plantings)
Soil drench (transplant water or immediately after transplanting)
Soil incorporated preplant
Bark spray

Azinphos-methyl is used as a foliar spray on a variety of field, vegetable, fruit and nut crops. Major use sites include cotton, apples, peaches and almonds. Other registered uses include potatoes, tomatoes, pears and cherries, pistachio nuts, peas (field), sugarcane, onions, celery, spinach, broccoli, Brussels sprouts, cabbage, cauliflower, beans, soybeans, peppers, cucumbers, melons, citrus fruit, apricots, nectarines, plums, prunes, vetch, safflower, blackberries, blueberries, cranberries, grapes, strawberries, filberts, pecans, walnuts, wheat, grass, alfalfa, clover, artichokes, eggplant, crabapples, quinces, boysenberries, loganberries, raspberries, oats, rye, barley, birdsfoot trefoil, tobacco, ornamentals, and forests. (Refer to Appendix III. for usage rates and calculations of amount of active ingredient used). Approximately 70% of azinphos-methyl use is attributed to use on major orchard and cotton pests. The two largest usage sites are cotton and apples comprising about 34% and 24%, respectively, of annual azinphos-methyl usage. Recommended application rates for cotton range from 1/8 to 1/4 lb a.i. per acre and for apples 1-2 lbs a.i. per acre.

Azinphos-methyl is an important component of the Integrated Pest Management (IPM) programs in tree fruit producing states. Azinphos-methyl is considered to be only slightly toxic to certain predators of stone and pome fruit pests, and is not plant phytotoxic or persistent in the soil. Consequently, it is widely used in IPM programs in tree fruit producing states.

Overall, the usage has been declining in markets where the synthetic pyrethroids are being heavily used. Cotton and tomatoes are examples of this market shift. Azinphos-methyl is used in most areas of the U.S. where fruit, vegetable and nut crops are grown. The least likely area of significant usage is the corn belt. Azinphos-methyl usage in the future would depend to some degree on regulatory status of competing insecticides. Two of these, parathion and phosmet are also under review by the Agency.

III. AGENCY ASSESSMENT

A. SUMMARY

The Agency has reviewed data submitted to support the registration of azinphos-methyl. Numerous data gaps exist for azinphos-methyl. However, based on available data the Agency has reached the following conclusions. A detailed discussion of the points summarized below appears in Section B.

1. Azinphos-methyl is acutely toxic to humans via oral and dermal routes of exposure. The toxicity is manifiested as cholinesterase inhibition. Technical azinphos-methyl is classified as Toxicity Category I due to oral and dermal toxicity. Exposure can be reduced through imposition of protective measures including protective clothing requirements, restricted use classification, precautionary labeling, reentry intervals.

2. Valid data are not available at the present time to assess the potential of azinphos-methyl to cause oncogenic, teratogenic, or reproductive effects. Additional chronic data are required and further evaluation will be conducted.

3. Azinphos-methyl is acutely toxic to fish and wildlife. Until required data are developed and submitted, hazards can be reduced through labeling statements and restrictions to protect potentially exposed endangered species.

As a result of this review the Agency has identified data necessary to fully evaluate the human and environmental risks associated with the use of azinphos-methyl. These data must be developed in order to maintain registrations of products or register new products containing azinphos-methyl. A summary of these data gaps appears in Figure I. Please note that this is only a summary and complete details can be obtained by referring to the tables in Appendix I.

The Agency has also determined that certain label restrictions or revisions are necessary. These include:

Restricted Use Classification
Protective Clothing
Rotational Crop Restrictions
Reentry Intervals
Endangered Species Requirements

The Regulatory Position and Rationale section discusses the Agency's position on each of these restrictions and the Required Labeling section contains the specific language for each labeling requirement.

Figure 1- DATA GAP TABLE

(Please refer to the tables in Appendix I for detailed information regarding these requirements)

Toxicology

Technical Azinphos methyl

Acute Inhalation (Rat)
Delayed Neurotoxicity (Hen)
Chronic Toxicity (Rodent)
Oncogenicity (Rat)
Teratogenicity (Rat and Rabbit)
2 Generation Reproduction (Rat)
Mutagenicity Testing
General Metabolism Testing

Manufacturing Use Products

Acute Oral (Rat)
Acute Dermal (Rabbit)
Acute Inhalation (Rat)
Primary Eye Irritation (Rabbit)
Primary Dermal Irritation (Rabbit)
Dermal Sensitization (Guinea Pig)

End Use Products

Acute Inhalation
Acute Dermal

Environmental Fate/Exposure

-Re-entry
Foliar Dissipation
Soil Dissipation
Dermal Exposure
Inhalation Exposure
Special Testing - Glove Permeability

Photodegradation (Water & Soil)
Anaerobic Aquatic Metabolism Study*
Forestry Dissipation*
Rotational Crops (Confined)
Irrigated Crops Accumulation Study*
Accumulation in Non-target Organisms*

Ecological Effects

Acute Avian Oral Toxicity
Wild Mammal Toxicity
Avian Reproduction
Field Testing for Mammals & Birds
Acute Toxicity to Freshwater Invertebrates
Acute Toxicity to Estuarine and Marine Organisms
Fish Early Life Stage
Simulated or Actual Field Testing for Aquatic Organisms
Honey Bee Toxicity (residues on foliage)

Product Chemistry/Residue Chemistry

Product Chemistry
Plant & Animal Metabolism
Storage Stability
Residue Studies

(Refer to Appendix I for Specified Crops)

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* Data not needed if label clarifications are made.

(Refer to Appendix I for further information).

B. PRELIMINARY RISK ASSESSMENT

The Agency has reviewed azinphos-methyl data in the areas of acute toxicity, chronic toxicity, oncogenicity, reproductive effects, mutagenicity, environmental fate and exposure, and ecological effects. Numerous data gaps exist. The following assessment is based on available data and is subject to change when the results of the required studies are available for Agency Review.

1. Acute Toxicity

All liquid formulations at concentrations of greater than 13.5% were restricted to certified applicators in 1978. The pesticide Incident Monitoring System (PIMS) data and California data on human toxicity demonstrate the need for continued restriction of liquid formulations.

Based on available acute oral and dermal toxicity data, technical azinphos-methyl is classified as a Toxicity Category I chemical. Available acute data define the approximate LD_{50}s for both oral and dermal routes of exposure. The acute oral LD_{50} for male and female rats is 4.6 mg/kg and 4.4 mg/kg, respectively. Acute dermal LD_{50} values for rats range from 200 to 250 mg/kg for males and 155 mg/kg for females. The toxicity is manifested as cholinesterase inhibition.

There are several testing categories for which data are not available for the technical and formulated products. (Refer to Appendix I. for the product specific data requirement). The Agency is requiring data to satisfy these testing requirements and to determine appropriate labeling.

Acute human toxicity from azinphos-methyl was further evaluated by reviewing reports of deaths, hospitalizations and visits to physicians outside hospitals, from the PIMS reports and from the state of California.

The PIMS file, at the time of the search, contained 46,421 incident reports covering the period from 1966 to July 1981 (when PIMS was discontinued), with 230 incidents involving the use of azinphos-methyl.

Two groups of reports were distinguished. One group of 106 reports cited azinphos-methyl alone. The other group of 124 reports cited azinphos-methyl in combination with other ingredients.

Humans were involved in 71 incidents in which azinphos-methyl alone was cited as causing the alleged adverse effects. (These incidents may have involved one or more persons). Seven people were hospitalized, 102 received medical attention, and 12 were affected or involved but did not seek medical advice. In the 84 incidents involving humans in which azinphos-methyl was cited in combination with other ingredients, there was 1 fatality (confirmed suicide) , 29 people were hospitalized, more than 285 received medical attention and more than 27 were affected or involved and did not seek medical advice. An additional fatality, that may also be attributed to azinphos-methyl exposure, occurred in 1985 as the result of pesticide missue.

The presentation of information regarding incident exposure, circumstances and effects in PIMS reports is made with no reference to whether or not the occurrence has been confirmed to be the result of pesticide involvement.

During the period from 1966 to 1981, mixing, loading, spraying, flagging, and handling the pesticide comprised about 40 percent of the reported incidents where medical attention was received. In several cases, other pesticides were also listed. Since 1978 (when liquid formulations containing greater than 13.5% active ingredient were classified for restricted use) less than 10% of the incidents where medical attention was received involved mixers, loaders or applicators who reportedly used proper protective clothing and equipment. A variety of other incidents involving medical attention was reported as the result of accidents (17%); improper use, storage or safety equipment (6%); spray drift (21%); and reentry (6%) during the 1978-81 period reported from PIMS.

In addition to PIMS reports, the Agency reviewed data provided by California (the only state which enforces manditory reporting of occupational pesticide incidents). Based on these data, physicians treated an average of 5 azinphos-methyl poisonings each year from 1981 through 1985. An additional one case per year was reported as either skin or eye injury. Of the total 29 illnesses reported in this period, 10 involved applicators, 5 involved mixer-loaders, 7 were due to spray drift, 5 were due to exposure to field residues, and 2 were due to other causes. Between 1981 and 1985, five cases of occupational azinphos-methyl poisoning required that the patient be hospitalized.

The PIMS record and California data demonstrate that systemic poisoning to users can result from exposure to azinphos-methyl. The Agency is relying on these data to form a regulatory position to reduce exposure by continuing the restricted use classification and by imposing protective clothing requirements.

2. Chronic Toxicity

Cholinesterase inhibition is the most significant toxic effect identified with azinphos-methyl usage. A chronic feeding study in dogs showed cholinesterase as the primary toxic action of azinphos-methyl. In this study, four groups of 4 dogs each per sex were offered diets containing azinphos-methyl on a time weighted average as follows: 0 ppm (control); 5 ppm, 39.7 ppm, 135.7 ppm. Clinical signs appearing in high dose animals, included muscle tremors, drooping of the head, and staggering. The No Observed Effect Level (NOEL) in this study was 5ppm. No tumors were reported in any animals. A chronic feeding study is required in rats.

3. Oncogenic Effects

In an oncogenicity bioassay performed by the National Cancer Institute at Gulf South Research Institute, azinphos-methyl was administered in the diet of Osborne-Mendel rats. Two groups of 50 male rats each received either 78 or 156 ppm for 80 weeks. Two groups of 50 female rats each received either 62.5 or 125 ppm for 80 weeks. Concurrent control groups consisted of 10 animals per sex each. All animals were observed for an additional 34-35 weeks. Neoplasms of the thyroid gland and of the pancreas suggested, but did not provide sufficient evidence to conclude that azinphos-methyl is oncogenic to male Osborne-Mendel rats. (Because of the wide range of spontaneous incidence of the thyroid and pancreatic tumors in Osborne-Mendel rats, the Agency concluded that there is no clear link between the deveopment of tumors to the administration of azinphos-methyl). This study was judged to be inadequate for statistical evaluation of risk because only 10 concurrent control animals per sex were used. Additionally, the use of pooled control animals, as used in this study, was inadequate for comparison purposes because of the variation in the experimental conditions under which animals were studied. A valid rat study meeting guideline requirements is required to determine the oncogenic potential of azinphos-methyl. Azinphos-methyl was not shown to be oncogenic in female Osborne-Mendel rats in this study.

An acceptable mouse oncogenicity study, run concurrently by NCI with the Osborne-Mendel rat study as discussed above, used 50 male and 50 female B6C3F1 mice. Male mice received dietary doses of 31.3 or 62.5 ppm and female mice received dietary doses of 62.5 or 125 ppm for 80 weeks. A concurrent control group consisted of ten mice of each sex and a pooled control group consisted of 130 males and 120 females. The animals were observed for an additional 13 weeks. The test results demonstrated that no incidence of tumors could be attributed to azinphos-methyl exposure.

A new mouse study conducted by Mobay Chemical Corporation, which is undergoing Agency evaluation, indicates that azinphos-methyl was negative for oncogenicity in CD1 mice. Azinphos-methyl was fed to groups of 50 male and 50 female mice at doses of 0, 5, 20 and 40 ppm for two years. The Agency's preliminary review indicates that no statistically significant increase in tumor incidence could be attributed to ingestion of azinphos-methyl. Survival rates were similar for all groups. There was no azinphos-methyl related effect except that of cholinesterase inhibition.

4. Human Exposure

Environmental Health Directorate, Health and Welfare Canada has provided the Agency with azinphos-methyl human exposure monitoring studies (GS0235057) conducted under their supervision. The Canadian studies involved foliar application of an azinphos-methyl 50% wettable powder formulation in orchards in British Columbia, Ontario, and Nova Scotia. The 23 study participants who mixed, loaded and applied the chemical wore cotton pants, long-sleeved shirts, cotton coveralls, respirators and protective gloves.

Urine samples were taken for 72 hours post-application and analyzed for dimethylthiophosphate (DMTP), the primary urinary metabolite of azinphos-methyl. The levels of urinary DMTP were significantly correlated with amount of azinphos-methyl mixed and sprayed. The overall mean internal dosage based on the 23 replicates was 1.2 mg azinphos-methyl per kilogram of of active ingredient handled.

Usage data indicate that during typical orchard use as a foliar insecticide, users may handle from 7.5 to 17.5 pounds of azinphos-methyl active ingredient per day in the United States. Based upon these data, the daily dosage received during mixing, loading, and application will range from 0.058 to 0.14 mg/kg/day (based on a 70 kg individual), assuming the use of protective gloves and cotton coveralls, but not respirators.

Foliar and soil dissipation, and dermal and inhalation exposure reentry data are required to fully access reentry exposure. A glove permeability study is required for the liquid formulation and the most concentrated spray solution using the wettable powder formulation. The glove permeability study must conform to "Standard Test Method for Resistance of Protective Clothing Materials to Permeation by Hazardous Liquid Chemicals" by the American Society for Testing and Materials.

5. Ecological Effects

Birds

Available acute oral avian toxicity studies are considered supplemental because they do not follow Agency guidelines for minimum numbers of dosage levels, for minimum numbers of birds per species, and for many other current test requirements. These data indicate that azinphos-methyl is moderately toxic to several avian species when administered orally in a single dose. The LD_{50} values are as follows: Mallard Duck = 136 mg/kg, Bobwhite Quail = 60-120 mg/kg, Pheasant = 74.9 mg/kg, and Chukar partridge = 84.2 mg/kg.

Avian dietary toxicity studies demonstrate the variable toxicity of azinphos-methyl. Azinphos-methyl is "highly toxic" to bobwhite quail (LC_{50} = 488 ppm), "moderately toxic" to Japanese quail (LC_{50} = 639 ppm), and "slightly toxic" to ring-necked pheasant (LC_{50} = 1821 ppm), and mallard duck (LC_{50} = 1940ppm).

Based on theoretical calculations azinphos-methyl may pose an acute hazard to birds, particularly at high application rates. The Agency is requiring additional acute oral toxicity testing, avian reproduction studies, and extensive field monitoring to complete a hazard assessment.

Mammals

Available data on laboratory animals indicate that azinphos-methyl is very highly toxic to mammals. The Agency lacks field data to fully assess the acute toxicity of azinphos-methyl. The Agency is requiring laboratory testing with wild mammals and extensive field monitoring to complete a hazard assessment.

Aquatic Organisms

Freshwater invertebrate acute toxicity data indicate that azinphos-methyl is very highly toxic to all species tested (LC_{50} values range from 0.13 to 56 ug/ liter and species tested include sowbug, amphipod, crayfish, glass shrimp, stonefly, and daphnia).

Freshwater fish acute toxicty data indicate that azinphos-methyl is very highly toxic to moderately toxic (LC_{50} values range from 0.36 to 4,270 ug/ liter), depending on species tested, with most values in the very highly toxic range (less than 100 ug/l).

Exposure modeling for cotton, soybean, and apple use patterns showed that aquatic residues could exceed levels acutely toxic to many aquatic organisms. This could be expected for virtually all other use sites as well, however, exposure modeling is not available for all sites.

PIMS reports, covering the period from 1966 through 1981, were reviewed to evaluate the extent of acute toxicity to freshwater fish from field usage of azinphos-methyl. All fifteen reports of fish kills, where azinphos-methyl alone was suspected, occurred prior to 1974.

For the period 1978-1985, seven additional fish kills, citing azinphos-methyl, alone, were obtained at the Agency's Office of Water.

The Agency is requiring additional aquatic acute and chronic toxicity testing as well as extensive aquatic field monitoring to assess the extent of exposure and hazard.

Wildlife Exposure and Hazard

Theoretical calculations and modeling indicate that azinphos-methyl has the capacity to cause adverse effects to wildlife. The hazard potential for any application rate appears to be greater for wild mammals and aquatic organisms than for birds.

The Agency is requiring that extensive field monitoring studies be conducted before risk assessment can be completed. Additionally, the Agency has identified use patterns and endangered species for which precautionary labeling is required. (Refer to Section IV.D. for the designated species).

C. OTHER SCIENCE FINDINGS

1. Metabolism

There are no valid metabolism studies available. These data are required.

2. Reproductive/Teratogenic Effects

There are no valid reproduction or teratology studies available to assess these effects from azinphos-methyl exposure. A mouse reproduction study suggested that animals given 0, 5, 10, or 25 ppm of azinphos-methyl showed no adverse effects over three generations. However, this study was found to be invalid due to reporting deficiencies and the Agency is requiring reproductive and teratology studies.

3. Mutagenic Effects

To assess the mutagenic potential of a chemical, the Agency requires that the following tests be performed to address the three categories of possible genetic effects :
(1) gene mutation, (2) chromosomal aberration and
(3) unscheduled DNA synthesis. No data are available on gene mutation and chromosomal abberation. An acceptable unscheduled DNA synthesis study demonstrated that azinphos-methyl does not induce unscheduled DNA synthesis in rat hepatocytes.

4. Environmental Fate

Available data indicate that azinphos-methyl exhibits low soil mobility and low leaching potential and, therefore, will not pose a hazard from leaching to the groundwater. Field dissipation studies demonstrate that azinphos-methyl is not persistent and 90% is degraded within 30 days. Under aerobic conditions, azinphos-methyl breaks down in soil to a azinphos-methyl oxygen analog, mercaptomethyl benzazimide, benzazimide, hydroxlymethyl benzazimide, and bis-methyl benzazimide sulfide.

The available data are insufficient to fully assess the environmental fate of azinphos-methyl. Photodegradation and rotational crops studies are required to be conducted and submitted to the Agency. If label clarifications, as noted in Appendix I (Table A) are made, additional data will not be required.

D. TOLERANCE REASSESSMENT

1. Tolerances issued.

Tolerances have been established for residues of azinphos-methyl (per se) in a variety of raw agricultural commodities, in meat, fat and meat byproducts (refer to 40 CFR 180.154 and 40 CFR 180.154a for listing of tolerances), and in processed food (21 CFR 193.150) and feed (21 CFR 561.180). No Mexican tolerances have been established for azinphos-methyl.

Commodity	U.S.	Canadian	Codex
Alfalfa	2.0	0.1	2.0
Alfalfa,hay	5.0	-	-
Almonds	0.3	-	0.2
Almonds,hulls	10.3	-	10.0
Apples	2.0	2.0	1.0
Apricots	2.0	2.0	2.0
Artichokes	2.0	0.5	0.5
Barley,grain	0.2	0.1	0.2
Barley,straw	2.0	0.1	-
Beans(dry)	0.3	2.0	0.5
Beans(snap)	2.0	2.0	0.5

Birdsfoot Trefoil	2.0	0.1	-
BirdsfootTrefoil,hay	5.0	0.1	-
Blackberries	2.0	2.0	1.0
Blueberries	5.0	2.0	1.0
Boysenberries	2.0	2.0	1.0
Broccoli	2.0	1.0	1.0
Brussels Sprouts	2.0	1.0	1.0
Cabbage	2.0	1.0	0.5
Cattle,fat	0.1	-	-
Cattle,meat by product	0.1	-	-
Cattle,meat	0.1	-	-
Cauliflower	2.0	0.5	0.5
Celery	2.0	0.5	2.0
Cherries	2.0	1.0	1.0
Citrus fruits	2.0	2.0	2.0
Clover	2.0	0.1	-
Clover,hay	5.0	-	-
Cottonseed	0.5	-	0.2
Crabapples	2.0	-	1.0
Cranberries	2.0	-	-
Cucumbers	2.0	0.5	0.5
Eggplant	0.3	-	0.5
Filberts	0.3	-	-
Goats,fat	0.1	-	-
Goats,meat by product	0.1	-	-
Goats,meat	0.1	-	-
Gooseberries	5.0	-	-
Grapes	5.0	5.0	4.0
Grass,pasture	2.0	0.1	-
Grass,pasture,hay	5.0	-	-
Horses,fat	0.1	-	-
Horses,meat by products	0.1	-	-
Horses,meat	0.1	-	-
Kiwi fruit	10.0	0.4	4.0
Loganberries	2.0	2.0	1.0
Melons	2.0	-	2.0
Nectrines	2.0	-	1.0
Nut,Pistachio	0.3	-	-
Oats,grain	0.2	0.1	0.2
Oats,straw	2.0	-	-
Onions(green)	2.0	1.0	0.5
Parsley(leaves)	5.0	-	0.5
Parsley(roots)	2.0	-	0.5
Peaches	2.0	2.0	4.0
Pears	2.0	2.0	1.0
Peas,black-eyed	0.3	-	0.5
Pecans	0.3	-	-
Peppers	0.3	0.2	0.5
Plums	2.0	1.0	1.0
Potatoes	0.3	0.1	0.2
Quinces	2.0	2.0	1.0
Raspberries	2.0	2.0	1.0
Rye,grain	0.2	0.1	0.2
Rye,straw	2.0	0.1	-

Commodity	U.S.	Canadian	Codex
Sheep,fat	0.1	-	-
Sheep,meat by product	0.1	-	-
Sheep,meat	0.1	-	-
Spinach	2.0	2.0	0.5
Strawberries	2.0	1.0	1.0
Sugarcane	0.3	-	-
Tomatoes	2.0	1.0	0.5
Walnuts	0.3	0.1	-
Wheat,grain	0.2	0.1	0.2
Wheat,straw	2.0	0.1	-
Milk	0.04	-	-
Soybean oil	1.0	-	-
Dried citrus	5.0	-	-
Sugarcane bagasse	1.5	-	-
Soybeans	0.2	0.2	-

2. Residue Data.

The residue data reviewed in support of these azinphos-methyl tolerances are:

a. Data on the nature of the residues in both plants and and animals, including identification of major metabolites and degradates of azinphos-methyl. The available plant metabolism data in which residues were most completely identified are not adequate because characterization of residues was conducted only in kidney bean plants. The limited data do show that ^{14}C-residues occur in untreated shoot portions following foliar applications of ^{14}C azinphos-methyl. Labelled residues are present in bean seedlings germinated from ^{14}C azinphos-methyl treated seed and in shoots of beans following root exposure to hydroponic solutions that contain ^{14}C azinphos-methyl. The parent compound, azinphos-methyl, azinphos-methyl oxon, dimethylbenzazimide sulfide, dimethyl benzazimide disulfide and benzazimide have been identified in extracts of bean leaves.

Tolerances of azinphos-methyl are currently expressed as residues of azinphos-methyl _per se_. The nature of the residue of azinphos-methyl in animals is not adequately understood because the available data fail to characterize total terminal residues in animal tissue. Upon receipt of the required plant and animal data, the tolerance will be reevaluated.

b. Analytical methodology for determining the levels of residues of azinphos-methyl in plants and animals is adequate for data collection for residues in plant commodities and in animal tissues and milk. (If additional metabolites of concern are found in plants and animals, additional data may be required).

c. Storage stability data demonstrate that residues of azinphos-methyl are stable in or on frozen plant commodities for up to 72 weeks when stored at -18 to -23°C, in milk samples stored at -23°C for up to 4 weeks (azinphos-methyl and azinphos-methyl oxon), and in liver samples stored at -22°C for up to 4 weeks (azinphos-methyl). Residues of azinphos-methyl oxon are stable in liver samples at -23°C for one week. Additional storage stability data are required in order to evaluate the adequacy of numerous established tolerances.

d. Data on the magnitude and levels of residues of azinphos-methyl in individual raw agricultural commodities, animal products, and processed food and feed items are sufficient to determine the adequacy of the established tolerances for residues of azinphos-methyl in potatoes, parsley, pistachios, sugarcane and sugarcane bagasse. There are not sufficient data available to ascertain the adequacy of the established tolerances for residues in or on onions, celery, spinach, broccoli, Brussels sprouts, cabbage, cauliflower, beans, soybeans, peppers, tomatoes, cucumbers, melons, citrus fruit, apples, apricots, cherries, nectarines, peaches, plums, blackberries, blueberries, cranberries, grapes, strawberries, almonds, almond hulls, filberts, pecans, walnuts, wheat grain, wheat straw, pasture grass, alfalfa, clover, artichokes, cottonseed, kiwi fruit, eggplant, crabapples, pears, quinces, boysenberries, loganberries, raspberries, oat grain, rye grain, barley grain, oat straw, rye straw, barley straw, birdsfoot trefoil, soybean oil, and dried citrus pulp.

Because of the extensive residue chemistry data gaps, the Agency cannot conduct a tolerance reassessment until the required data are submitted and reviewed.

2. Toxicology

A 2-year rat feeding study with a NOEL of 5 ppm, based on cholinesterase inhibition had originally been used to support the established tolerances for residues of azinphos-methyl. Using a ten-fold safety factor, the Acceptable Daily Intake (ADI) was calculated to be 0.0250 mg/kg/day (1 ppm in the rat diet is equivalent to 0.05 mg/kg/body weight/day), giving an MPI (Maximum Permissible Intake) of 1.5 mg/day for a 60 kg person. The Theoretical Maximum Residue Contribution (TMRC) for all published tolerances was calculated to be 0.6678 mg/kg/day for a 1.5 kg diet. The TMRC thus utilized 45.19% of the ADI. This study was not acceptable to support registration, but may be upgraded upon submission of additional information.

The Agency has, therefore, calculated a Provisional Limiting Dose (PLD), which is similar to the ADI except that a greater safety or "uncertainty" factor is used because the data base is now only minimally adequate to support existing tolerances considering the lack of the chronic rat study. The PLD is a temporary value that is used until the data base is completed.

The PLD is based on a two year dog feeding study described earlier. This study demonstrated a NOEL of 5 ppm (1 ppm in the dog diet is equivalent to 0.025 mg/kg/day) and uses an uncertainty factor of 100 (due to the effect of cholinesterase inhibition and the reduced data base). This yields a Maximum Permissible Intake (MPI) of 0.075 mg/kg/day for a 60 kg person for a TMRC of 0.6678 mg/kg/day per 1.5 kg of diet.

The PLD is now 899% of the MPI. This value is greatly inflated when compared to actual dietary residues expected in practice, and is due solely to the additonal 10-fold uncertainty factor applied for the reduced data base and the two-fold increase in sensitivity of the dog compared to that of the rat (i.e., 1 ppm of a toxicant in the rat diet is equivalent to 2 ppm in the dog diet).

When additional chronic feeding studies necessary to establish an ADI are submitted, the percentage of the ADI utilized will be adjusted and the uncertainty factors may be eliminated as data gaps are filled. In addition, FDA residue monitoring data from 1978 to 1985 demonstrate that less than one percent of the samples taken from azinphos-methyl treated crops showed detectable residues and all residue levels were well below established tolerances. The Agency concludes that the present TMRC, which is a measure of the upper limit of possible dietary exposure, is far greater than what is reasonably likely to be found in practice. Because of the extensive residue chemistry and toxicology data gaps, the Agency cannot conduct a full tolerance reassessment. The tolerances will be reassessed when the required data are submitted and reviewed.

IV. REGULATORY POSITION AND RATIONALE

A. REGULATORY POSITIONS AND RATIONALES

Based on review and evaluation of all available data and other relevant information on azinphos-methyl, the Agency has made the following determinations:

1. The Agency is not placing azinphos-methyl into Special Review at this time.

Rationale:

While the Agency has concerns for the hazard to both humans and wildlife due to acute toxicity, the Agency is not initiating a Special Review at this time.

For wildlife effects, theoretical calculations and modeling indicate that azinphos-methyl has the capacity under various use patterns and application rates to cause effects (i.e. non-target mortality) to fish, birds and mammals. There is, however, limited field data to support the finding that significant adverse effects exist for terrestrial and aquatic wildlife. The Agency is requiring extensive field monitoring data to define the extent of exposure and hazard. Upon receipt and review of the required data, the Agency will complete a hazard assessment.

Incident data and human toxicity data on the technical product demonstrate that systemic poisoning to users can result from exposure to azinphos-methyl. Through the continued restricted use classification for liquid formulations greater than 13.5%, the requirement of acute toxicity data to determine the appropriate precautionary labeling for end-use products, and the imposition of protective clothing and work safety statements, the Agency believes that hazards posed by acute toxicity will be mitigated.

2. No significant new tolerances and significant new food uses will be granted until the Agency has received data sufficient to evaluate the dietary exposure to azinphos-methyl.

Rationale: The Agency is concerned that the PLD is now 899% of the MPI. Residue chemistry and toxicology data bases for azinphos-methyl are not sufficient to assess the exisiting tolerances. Plant and animal metabolism data and residue data on various commodities are required. The pertinent toxicology data requirements include: chronic feeding/oncogenicity, teratology, reproduction and mutagenicity. (Refer to Appendix I, Table A, for a listing of residue chemistry and toxicology data required). Until these data are submitted and reviewed, the Agency cannot perform a tolerance reassessment.

3. The Agency will continue to restrict all liquid formulations of azinphos-methyl with concentrations greater than 13.5% active ingredient. In addition, registrants must either classify all products for restricted use due to acute toxicity or submit dermal and inhalation data to support the appropriate toxicity category. (Note: The results of the data may indicate continued restricted use classification).

Rationale: The restricted use classification was originally imposed on all azinphos-methyl liquid formulations greater than 13.5% due to inhalation toxicity. Because these data are no longer acceptable, the Agency, in order to minimize risk to mixers, loaders, and applicators, will continue to classify all liquid formulations of azinphos-methyl with concentrations greater than 13.5% as restricted use pesticides. Because of the number of reported incidents and the acute toxicity of technical azinphos-methyl, the Agency is requiring data to determine the appropriate toxicity category and precautionary labeling for all azinphos-methyl products. Registrants may choose not to submit these data, in that case, these products, will be classified as restricted use.

4. The Agency has classified azinphos-methyl as a class D oncogen, meaning that there are inadequate data to determine whether azinphos-methyl is an oncogen. A rat oncogenicity/chronic feeding study and mutagenicity studies must be submitted. This classification will be reevaluated when the required data are submitted.

Rationale:

An NCI rat study was not conclusive regarding oncogenicity but indicated that azinphos-methyl may produce rare pancreatic tumors and thyroid tumors in male rats. However, because there were insufficient numbers of control animals, the significance of these results is not known. Two separate mouse studies were negative for oncogenic effects. Since mutagenicity is an indicator of potential oncogenicity, mutagenicity studies are being required.

5. Endangered species labeling is required for certain azinphos-methyl uses.

Rationale: Azinphos-methyl is toxic to certain fish, birds, mammals and aquatic invertebrates which reside in areas where azinphos-methyl is likely to be used. The Agency, in an attempt to limit use of azinphos-methyl in areas where its use may be detrimental to endangered species, is requiring that endangered species information be included on labeling of end-use products which contain certain uses for forests, crops and range and pastureland. The required labeling is based on Biological Opinions by the Office of Endangered Species (OES) of the Fish and Wildlife Service, U.S. Department of Interior. (Refer to Section IV. D. for the required endangered species labeling).

6. A 24 hour reentry interval, as established in 1974 under 40 CFR 170.3(b)(2), will remain in effect. The Agency is requiring reentry data (refer to Appendix A) to determine the most effective reentry interval for azinphos-methyl.

Rationale:

Due to the Agency's continuing concern over the potential for exposure to farmworkers reentering azinphos-methyl treated fields, this interval will remain in effect. Based upon the evaluation of the required data, the Agency may need to revise this reentry interval.

7. The Agency is imposing an interim crop rotation restriction of 6 months for root crops not registered for use with azinphos-methyl and 30 days for all other crops not registered for use with azinphos-methyl until the required crop rotation data are submitted.

Rationale: Agency files contain data that had reporting deficiencies and did not follow Agency guidelines and were, therefore, classified as supplemental data. These data indicate that no residues of azinphos-methyl or azinphos-methyl oxygen analog were detected in grain, pod and leafy vegetable crops that were planted 30 days after azinphos-methyl applications. Azinphos-methyl residues were detected in root crops planted 120 days after applications. Because these studies were not carried out past 120 days, the Agency is imposing the 6 month crop rotation restriction on root crops planted in azinphos-methyl treated fields.

Until the required crop rotation data can be evaluated, the Agency is imposing the crop rotation restrictions in order to assure that excess residues of azinphos-methyl do not occur in subsequently planted crops.

8. The Agency is requiring a glove permeability test for liquid and wettable powder formulations of azinphos-methyl.

Rationale: Gloves can greatly reduce dermal exposure. While gloves are required for handling azinphos-methyl, there are no data demonstrating which materials best limit exposure. The Agency is requiring the glove permeability study in order to determine which materials are best suited for this use.

9. The Agency is requiring the addition of the telephone number of the National Pesticide Telecommunications Network to all azinphos-methyl products that are classified as Toxicity Category I and II (bearing the danger or warning signal words).

Rationale: The telephone number is included in order to provide a source of first aid information in the event of an exposure accident.

10. The Agency is requiring that end-use product labeling contain personal hygiene information and requirements for cleaning of protective clothing and equipment after working with azinphos-methyl products. (Refer to Section IV.D. for specific labeling requirements).

Rationale: Because of the toxicity of many of these products and the number of incidents reported, the Agency believes this requirement is necessary to prevent poisonings of workers or other household members through secondary exposure to contaminated personal clothing.

11. The Agency is requiring that all azinphos-methyl end-use product labeling must contain work safety rules, precautionary statements, and protective clothing statements. (Refer to Section IV.D. for specific labeling requirements).

Rationale: These precautionary labeling statments provide specific guidance for persons handling azinphos-methyl products.

These statements describe the required protective clothing and equipment for use, as well as procedures for minimizing exposure to pesticide contaminated materials.

12. The Agency is prohibiting the use of human flaggers during aerial application, unless they are in an enclosed vehicle.

Rationale: The Agency is imposing this requirement to minimize hazard to flaggers because human flaggers face a risk of exposure by direct contact or through drift during aerial application.

13. While the required data are being developed, currently registered manufacturing use products (MP's) and end use products (EP's) containing azinphos-methyl as the sole active ingredient may be sold, distributed, formulated and used subject to the terms and conditions specified in this standard. Registrants must provide or agree to develop and provide additional data, as specified in the Data Appendices, in order to maintain existing registrations.

Rationale: Under FIFRA, the Agency may choose not to cancel or withhold registration if data are missing or inadequate [see FIFRA Sec. 3(C)(2)(B) and 3(c)(7)]. The issuance of this standard provides a mechanism for identifying data needs. These data will be reviewed and evaluated, after which the Agency will determine if additional regulatory actions are necessary.

B. CRITERIA FOR REGISTRATION

To be registered or reregistered under this standard, manufacturing use products (MP) must contain azinphos-methyl as the sole active ingredient, bear required labeling, and conform to the product composition, acute toxicity limits, and use pattern requirements listed in this document.

The applicant for registration or reregistration of manufacturing use products subject to this standard must comply with all terms and conditions described, including submission of an up-to-date Confidential Statement of Formula, submission of revised labeling, commitment to fill data gaps on the schedules as specified by the Agency and, when applicable, offer to pay compensation as required by sections 3 (c)(1)(D) and 3(c)(2)(D) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as ameneded, 7 U.S.C. 136 (c)(2)(D). Registrants of end-use products who qualify for the Formulator's Exemption must submit five (5) copies of draft labeling incorporating the unique label statements identified in Section D.

C. ACCEPTABLE RANGES AND LIMITS

1. Product Composition Standard

To be registered or reregistered under this standard, manufacturing-use products (MPs) must contain azinphos-methyl as the sole active ingredient. Each MP formulation proposed for registration must be fully described with an appropriate certification of limits, stating maximum and minimum amounts of the active ingredient and inert ingredients which are present in products, as well as impurities found at greater than 0.1%.

2. Acute Toxicity Limits

The Agency will consider registration of technical grade and manufacturing products containing azinphos-methyl provided that the product labeling bears appropriate precautionary statements for the acute toxicity category in which each product is placed.

3. Use Patterns

To be registered under this standard, manufacturing-use products must be labeled for formulation into other manufacturing-use products on into end-use products bearing federally registered uses. The Use Index in Appendix III, lists all registered uses, as well as approved maximum application rates and frequencies.

D. REQUIRED LABELING

All products must bear appropriate labeling as specified in 40 CFR 162.10, PR Notice 83-2 and 83-3 and below. Appendix II contains information on label requirements.

Pesticide products containing azinphos-methyl as an active ingredient may not be released for shipment by the registrant after October 31, 1987 unless the product bears amended labeling which complies with the requirement of this Standard.

Pesticide products containing azinphos-methyl as an active ingredient may not be distributed, sold, offered for sale, held for sale, shipped, delivered for shipment, or received and (having been so received) delivered or offered to be delivered by any person after October 31, 1988, unless the product bears amended labeling which, approved by EPA, complies with the requirements of this Standard.

The following information must appear on manufacturing and end use products:

Ingredients Statement

The ingredient statement for all azinphos-methyl products must list the active ingredient as:

ACTIVE INGREDIENTS:

O,O-dimethyl-s-[(4-oxo-1,2,3-benzotriazin-3(4H)-yl)methyl] phosphorodithioate.............................. ________%

INERT INGREDIENTS .... ________%

Manufacturing Use Product Labeling

1. Use Pattern Statements

All manufacturing-use products must state that they are intended for formulation into end-use products for acceptable use patterns. Labeling must specify sites, which are listed in Use Patterns, Appendix III. However, no use may be included on the label where the registrant fails to agree to comply with the data requirements in TABLE A for that use pattern.

2. Environmental Hazards Statement

The following revised environmental hazard statement must appear on all manufacturing-use product labels:

> "This pesticide is extremely toxic to fish and wildlife. Do not discharge effluent containing this product directly into lakes, streams, ponds, estuaries, oceans or public waters unless this product is specifically identified and addressed in an NPDES permit. Do not discharge effluent containing this product to sewer systems without previously notifying the sewage treatment plant authority. For guidance, contact your State Water Board or Regional Office of the Environmental Protection Agency."

End Use Product Labeling

a. Environmental Hazards Statements

"This pesticide is extremely toxic to fish and wildlife.

Do not apply directly to water or wetlands (swamps, bogs, marshes, and potholes). Do not contaminate water by cleaning of equipment or disposal of wastes. Drift and runoff from treated areas may be hazardous to aquatic organisms in neighboring areas."

For granular products add:

"Cover or incorporate granules that are spilled during loading or are visible on soil surface in turn areas."

b. Endangered Species

The paragraph below must appear on all end-use product labels that contain forest, crop, range and pastureland (east of Mississippi) uses:

"ENDANGERED SPECIES RESTRICTIONS

The use of any pesticide in a manner that may kill or otherwise harm an endangered or threatened species or adversely modify its habitat is a violation of federal laws. The use of this product is controlled to prevent death or harm to endangered or threatened species that occur in the following counties or elsewhere in their range. Before using this pesticide in the following counties you must obtain the EPA Crop and Rangeland/Pastureland Endangered Species Bulletins. The use of this pesticide is prohibited in these counties unless specified otherwise in the Bulletins. The EPA Bulletins are available from either your County Agricultural Extension Agent, the Endangered Species Specialist in your State Wildlife Agency Headquarters or the appropriate Regional Office Headquarters or the appropriate Regional Office of either the US Fish and Wildife Service (FWS) or the US Environmental Protection Agency. THESE BULLETINS MUST BE REVIEWED PRIOR TO PESTICIDE USE."

In addition to the paragraph above, end use product labeling must contain the following specific species listing and location information for forest, crop and range and pastureland (east of the Mississippi) uses:

AZINPHOS-METHYL ENDANGERED SPECIES LABEL INFORMATION FOR FOREST USES

ENDANGERED SPECIES RESTRICTIONS

STATE (regional office FWS) Species	COUNTY
ALABAMA (Atlanta, GA.)	
Red-cockaded woodpecker	Baldwin, Bibb, Calhoun, Chilton, Clay Cleburne, Covington, Escambia, Dale, Jefferson, Lawrence, Macon, Perry, Shelby, St. Clair, Talladega, Tuscaloosa and Winston
Slackwater darter	Lauderdale, Limestone and Madison
Snail darter	Jackson and Madison
Freshwater mussels	Colbert, Jackson, Marshall and Morgan
ARIZONA (Albuquerque, N.M.)	
Arizona (Apache) trout	Apache, Greenlee and Graham
Gila trout	Cochise, Santa Cruz, Pinal, Graham and Pima
Bonytail chub	Mohave
ARKANSAS (Atlanta, GA.)	
Freshwater mussels	Clay, Clark, Cross, Lawrence, Randolph, Sharp and St. Francis
Red-cockaded woodpecker	Ashley, Calhoun, Clark, Columbia, Hempstead, Lafayette, Monroe, Ouachita, Polk, Scott and Union
CALIFORNIA (Portland, OR.)	
Little Kern golden trout	Tulare
Paiute cutthroat trout	Alpine, Madera and Mono
COLORADO (Denver, CO.)	
Greenback cutthroat trout	Boulder, Larimer, Gilpin, Park and Fremont
Bonytail chub Humpback chub Colorado Squawfish	Routt, Moffat, Rio, Blanco, Garfield, Mesa and Delta
FLORIDA (Atlanta, GA.)	
Red-cockaded woodpecker	Alachua, Baker, Bay, Brevard, Charlotte, Citrus, Clay, Columbia, Duval, Franklin, Glades, Gulf, Hernando, Highlands, Lee, Leon, Levy, Liberty, Marion, Martin, Okaloosa, Okeechobee, Osceola, Palm Beach, Pasco, St. Johns, Santa Rosa, Wakulla and Walton
Okaloosa darter	Okaloosa and Walton

Forest Use (continued)

STATE Species	COUNTY
GEORGIA (Atlanta)	
Red-cockaded woodpecker	Appling, Baldwin, Brantley, Charlton, Chattahoochee, Clarke, Clinch, Decatur, Floyd, Glynn, Grady, Harris, Jasper, Jenkins, Jones, Pierce, Putnam, Screven, Tattnall, Telfair, Thomas, Toombs, Turner, Ware, Washington and Wilkes
Snail darter	Catoosa
KENTUCKY (Atlanta, GA.)	
Freshwater mussels	Ballard, Edmundson, Jackson, Laurel, Marshall, McCracken, Pulaski, Rockcastle, Warren and Wayne
Red-cockaded woodpecker	Laurel and McCreary
LOUISIANA (Atlanta, GA.)	
Red-cockaded woodpecker	Allen, Beauregard, Bienville, Bossier, Caddo, Calcasieu, Catahoula, Claiborne, Grant, La Salle, Morehouse, Natchitoches, Ouachita, Rapides, St. Tammany, Tangipahoa, Union, Vernon and Washington
MARYLAND (Newton Corners, MA.)	
Red-cockaded woodpecker	Dorchester
Maryland darter	Harford
MICHIGAN_(Twin Cities, MN.)	
Kirtland's warbler	Crawford, Kalkaska, Oscoda, Ogemaw, Roscommon and Wexford
MISSISSIPPI (Atlanta, GA.)	
Red-cockaded woodpecker	Choctaw, Copiah, Franklin, Harrison, Hinds, Jackson, Jones, Lauderdale, Leake, Madison, Marion, Noxubee, Oktibbeha, Pearl River, Scott, Smith, Stone, Wayne, Wilkinson and Winston
NORTH CAROLINA (Atlanta, GA.)	
Red-cockaded woodpecker	Beaufort, Bertie, Bladen, Brunswick, Cumberland, Gates, Harnett, Hertford, Hoke, Hyde, Jones, Montgomery, Moore, Northampton, Onslow, Pamlico, Perquimans, Pitt, Richmond, Wake and Wayne
Spotfin chub	Macon and Swain

Forest Use (continued)

STATE Species	COUNTY
OKLAHOMA (Albuquerque, N.M.)	
Red-cockaded woodpecker	Bryan, Latimer, Le Flore, McCurtain, Pittsburg and Pushmataha
Leopard darter	Pushmataha and McCurtain
OHIO (Twin Cities, MN.)	
Scioto madtom	Champagne, Franklin, Logan, Madison, Pikaway and Union
SOUTH CAROLINA (Atlanta, GA.)	
Red-cockaded woodpecker	Aiken, Barnwell, Beaufort, Berkeley, Calhoun, Charleston, Chesterfield, Clarendon, Colleton, Darlington, Dillon, Dorchester, Edgefield, Florence, Georgetown, Hampton, Horry, Laurens, Lee, Lexington, Orangeburg, Richland, Sumter and Williamsburg
TENNESSEE (Atlanta, GA.)	
Freshwater mussels	Blount, Claiborne, Decatur, Franklin, Hancock, Hardin, Lincoln, Loudon, Marshall, Maury, Rhea, Roane, Scott, Sequatchie, Smith and Sullivan
Red-cockaded woodpecker	Blount, Campbell, Cumberland and Morgan
Slackwater darter	Lawrence and Wayne
Slender chub	Claiborne and Hancock
Spotfin chub	Cumberland, Fentress and Morgan
Snail darter	Loudon, Meigs, Polk, Hamilton, Marion, Bradley and Knox
Yellowfin madtom	Claiborne, Hancock and Monroe
TEXAS (Albuquerque, N.M.)	
Red-cockaded woodpecker	Angelina, Cass, Cherokee, Hardin, Houston, Jasper, Montgomery, Nacogdoches, Newton, Polk, Sabine, San Augustine, San Jacinto, Shelby, Trinity, Tyler and Walker
UTAH (Denver, CO.)	
Bonytail chub Humpback chub Colorado squawfish	Carbon, Duchesne, Emery, Garfield, Uintah, Grand, Kane, San Juan and Wayne

Forest Use (continued)

STATE Species	COUNTY
VIRGINIA (Newton Corners, MA.)	
Freshwater mussels	Lee, Russell, Scott, Smyth, Tazewell, Washington and Wise
Red-cockaded woodpecker	Prince George, Southampton, Surry and Sussex
Slender chub	Lee and Scott
Spotfin chub	Scott and Washington
Yellowfin madtom	Lee, Scott and Russell

AZINPHOS-METHYL ENDANGERED SPECIES LABELING INFORMATION FOR CROP USES

STATE (Regional office FWS) Species	COUNTY	
ALABAMA (Atlanta, GA.)	LAUDERDALE	MADISON
Slackwater darter	LIMESTONE	
Alabama cavefish	LAUDERDALE	
Freshwater mussels	COLBERT	MARSHALL
	JACKSON	MORGAN
ARIZONA (Albuquerque, N.M.)		
Woundfin	MOHAVE	
Gila topminnow	GRAHAM	SANTA CRUZ
ARKANSAS (Atlanta,GA.)	CLAY	RANDOLPH
Freshwater mussels	CLARK	SHARP
	CROSS	ST. FRANCIS
	LAWRENCE	
Leopard darter	POLK	
CALIFORNIA (Portland, OR.)		
Delta green ground beetle	SOLANO	
Valley elderberry longhorn beetle	MERCED SACRAMENTO	
Aleutian Canada goose	COLUSA	SUTTER
	MERCED	STANISLAUS
Kern primrose sphinx moth	KERN	
American peregrine falcon	HUMBOLT	SAN LUIS OBISPO
	LOS ANGELES	SAN MATEO
	MARIPOSA	SANTA CLARA
	MENDOCINO	SANTA CRUZ
	MONTEREY	SONOMA
	SAN DIEGO	TUOLUMNE
Blunt-nosed leopard lizard	FRESNO	MONTEREY
	KERN	SAN LUIS OBISPO
	KINGS	SANTA BARBARA
	MADERA	STANISLAUS
	MERCED	TULARE
Santa Cruz long-toed salamander	MONTEREY	SANTA CRUZ
Unarmored three-spine stickelback	LOS ANGELES	SANTA BARBARA
COLORADO (Denver, CO.)	BLANCO	MOFFAT
Colorado squawfish	DELTA	RIO
	GARFIELD	ROUTT
	MESA	
KENTUCKY (Atlanta, GA.)	BALLARD	McCRACKEN
Freshwater mussels	EDMUNDSON	PULASKI
	JACKSON	ROCKCASTLE
	LAUREL	WARREN
	MARSHALL	WAYNE
MICHIGAN (Twin Cities, MN.)		
American peregrine falcon	LEEVANAU	

Crop Uses (continued)

MINNESOTA (Twin Cities, MN.)		
American peregrine falcon	CHISAGO	WABASHA
	DAKOTA	WASHINGTON
	GOODHUE	WINONA
	HOUSTON	
MISSISSIPPI (Atlanta, GA.)	CLAIBORNE	
Bayou darter	COPIAH	
NEVADA (Portland, OR.)		
Woundfin	CLARK	
Pahranagat bonytail	LINCOLN	
Cui-ui	WASHOE	
Pahrump killifish	CLARK	WHITE PINE
NEW MEXICO (Albuquerque, N.M.)	CHAVES	
Pecos gambusia	EDDY	
OHIO (Twin Cities, MN.)	CHAMPAGNE	MADISON
Scioto madtom	FRANKLIN	PICKAWAY
	LOGAN	UNION
OKLAHOMA (Albuquerque, N.M.)	LEFLORE	
Leopard darter	MCCURTAIN	
OREGON (Portland, OR.)		
American peregrine falcon	CLACKAMUS	MARION
	DOUGLAS	UMATILLA
	HOOD RIVER	WASCO
	JACKSON	
TENNESSEE (Atlanta, GA.)	LAWRENCE	
Slackwater darter	WAYNE	
Freshwater mussels	BLOUNT	MARSHALL
	CLAIBORNE	MAURY
	DECATUR	RHEA
	FRANKLIN	ROANE
	HANCOCK	SCOTT
	HARDIN	SEQUATCHIE
	LINCOLN	SMITH
	LOUDON	SULLIVAN
TEXAS (Albuquerque, N.M.)	ARANSAS	GOLIAD
Attwater's Greater Prairie Chicken	AUSTIN	REFUGIO
	COLORADO	VICTORIA
	FORT BEND	
Commanche Springs pupfish	JEFF DAVIS	
	REEVES	
Pecos gambusia	JEFF DAVIS	REEVES
	PECOS	
Texas blind salamander	HAYS	
San Marcos salamander	COMAL	HAYS
San Marcos gambusia	HAYS	
Houston toad	BASTROP	HARRIS
	BURLESON	
Fountain darter	COMAL	HAYS

Crop Uses (continued)

UTAH (Denver, CO.) Woundfin	WASHINGTON	
Colorado squawfish	CARBON DUCHESNE EMERY GARFIELD GRAND	KANE SAN JUAN UINTAH WAYNE
VIRGINIA (Newton Corners, MA.) Freshwater mussels	LEE RUSSELL SCOTT SMYTH	TAZEWELL WASHINGTON WISE
WASHINGTON (Portland, OR.) American peregrine falcon	SKAMANIA	
WISCONSON (Twin Cities, MN.) American peregrine falcon	CRAWFORD DANE DOOR	RICHLAND SAUK TREMPEALEAU

AZINPHOS-METHYL LABELING INFORMATION FOR RANGE AND PASTURELAND USES EAST OF MISSISSIPPI

STATE (Regional Office FWS) Species	County (unless specified otherwise)
ALABAMA (Atlanta, GA.)	
Alabama cavefish	Lauderdale
Slackwater darter	Lauderdale, Limestone and Madison
Snail darter	Jackson and Madison
Watercress darter	Jefferson
Freshwater mussels	Colbert, Jackson, Marshall and Morgan and Monroe
ARKANSAS (Atlanta, GA.)	
Freshwater mussels	Clark, Clay, Cross, Lawrence, Randolph, Sharp and St. Francis
FLORIDA (Atlanta, GA.)	
Okaloosa darter	Okaloosa and Walton
Eastern indigo snake	Statewide
GEORGIA (Atlanta, GA.)	
Snail darter	Catoosa
Eastern indigo snake	S.E. Georgia
KENTUCKY (Atlanta, GA.)	
Freshwater mussels	Ballard, Edmundson, Jackson, Laurel, Marshall, McCracken, Pulaski, Rockastle, Warren and Wayne
Kentucky Cave shrimp	Edmundson and Hart
MARYLAND (Newton Corners, MA.)	
Maryland darter	Harford
MISSISSIPPI (Atlanta, GA.)	
Bayou darter	Claiborne and Copiah
Mississippi sandhill crane	Jackson
NORTH CAROLINA (Atlanta, GA.)	
Spotfin chub	Macon and Swain
OHIO (Twin Cities, MN.)	
Scioto Madtom	Champagne, Franklin, Logan, Madison, Pickaway and Union

Range and Pastureland (continued)

TENNESSEE (Atlanta, GA.)	
Slender chub	Claiborne and Hancock
Spotfin chub	Cumberland, Fentress and Morgan
Slackwater darter	Lawrence, Wayne,
Snail darter	Bradley, Hamilton, Knox, Loudon, Marion, Meigs and Polk
Yellowfin madtom	Claiborne, Hancock and Monroe
Freshwater mussels	Blount, Claiborne, Decatur, Franklin, Hancock, Hardin, Hawkins, Lincoln, Loudon, Marshall, Maury, Rhea, Roane, Scott, Sequatchie, Smith and Sullivan
VIRGINIA (Newton Corners, MA.)	
Slender chub	Lee and Scott
Spotfin chub	Scott and Washington
Yellowfin madtom	Lee, Russell and Scott
Freshwater mussels	Lee, Russell, Scott, Smyth, Tazewell, Washington and Wise

c. Reentry Statement

The following statement must appear on the labeling of agricultural end use products which are applied to crops whose culture may involve hand labor tasks:

"Do not enter treated areas for 24 hours after application unless protective clothing is worn, as described in the product labeling."

d. Restricted Use Statement

The following restricted use statement must appear on the front panel of all end-use labeling for liquid formulations with concentrations greater than 13.5%:

"RESTRICTED USE PESTICIDE
Due to acute toxicity

For retail sale to and use only by certified applicators or persons under their direct supervision and only for those uses covered by the certified applicator's certification".

As stated in Section IV. A., registrants of all azinphos-methyl end-use products will be given the option of either submitting acute toxicity data (refer to Appendix A for listing of data requirements) or restricting their products and revising their label(s) to include the restricted use statement above and the following precautionary language associated with Toxicity Category I products:

"Danger

Fatal if swallowed, inhaled or absorbed through the skin. Do not breath vapor, dust or spray mist. Do not get in eyes, on skin, or on clothing."

e. Rotational Crop Statement

All end-use products must have the following crop rotation statement:

> "Do not plant root crops other than those with registered azinphos-methyl uses in azinphos-methyl treated soil sooner than 6 months after the last application. Do not plant any other crop other than those with registered azinphos-methyl uses in treated soil sooner than 30 days after last applications".

f. Work Safety Rules

"If handled indoors provide mechanical exhaust ventilation.

Keep all unprotected persons, children, livestock, and pets away from treated areas or where there is danger of drift.

Do not rub eyes or mouth with hands. If you feel sick in any way, STOP work and get help right away. See First Aid section of the label.

For questions regarding further treatment, or information about the product, call the National Pesticide Telecommunications Network at 800-858-7378."

g. Protective Clothing and Work Safety Statements for all azinphos-methyl End-Use products :

Labeling for Products with Danger and Warning Signal words

"HANDLE THE CONCENTRATE ONLY WHEN WEARING THE FOLLOWING PROTECTIVE CLOTHING AND EQUIPMENT:

Wear a protective suit of one or two pieces that covers all parts of the body except the head, hands, and feet. Wear chemical resistant gloves, chemical resistant apron, and chemical resistant shoes, shoe coverings, or boots. Wear goggles or a face shield and a pesticide respirator approved by the National Institute for Occupational Safety and Health under the provisions of 30 CFR Part II.

If handling the concentrate with a closed system, long sleeved shirt and long-legged pants may be substituted

for the protective suit, and the respirator requirement is waived. (For liquid formulations only).
WEAR THE FOLLOWING PROTECTIVE CLOTHING DURING APPLICATION, EQUIPMENT REPAIR, EQUIPMENT CLEANING, DURING REENTRY TO TREATED AREAS, AND DISPOSAL OF THE PESTICIDE:

Wear a protective suit of one or two pieces that covers all parts of the body except the head, hands, and feet. Wear chemical resistant gloves and chemical resistant shoes, shoe coverings, or boots. Wear a chemical resistant hat during airblast application.

During application from an enclosed tractor cab or airplane cockpit, or other suitable vehicle in which the windows are rolled up, long sleeved shirt and long pants may be worn in place of the above protective clothing. Chemical resistant gloves must be available in the cab or cockpit and must be worn while exiting. This clothing is inadequate to protect you during equipment repair, equipment cleaning, re-entry, or during pesticide disposal.

IMPORTANT! BEFORE REMOVING GLOVES, WASH THEM WITH SOAP AND WATER. ALWAYS WASH HANDS, FACE, AND ARMS WITH SOAP AND WATER BEFORE SMOKING, DRINKING, EATING OR TOILETING.

After work, take off all clothing and shoes. Shower using soap and water. Do not wear contaminated clothing. Wash protective clothing and protective equipment with soap and water after each use. Respirators must be cleaned and filters replaced according to instructions included with the respirators. Personal clothing worn during use must be laundered separately from household articles. Clothing and protective equipment heavily contaminated or drenched with azinphos-methyl must be destroyed according to state and local regulations. HEAVILY CONTAMINATED OR DRENCHED CLOTHING CANNOT BE ADEQUATELY DECONTAMINATED.

During aerial application, human flaggers are prohibited unless in totally enclosed vehicle".

h. Protective Clothing and Work Safety Statements for End-Use Products that have "Caution" as the signal word:

"If handled indoors provide mechanical exhaust ventilation.

Keep all unprotected persons, children, livestock, and pets away from treated areas or where there is danger of drift.

Do not rub eyes or mouth with hands. If you feel sick in any way, STOP work and get help right away. See First Aid (Practical Treatment) section of the label.

When handling this product wear long pants and long sleeved shirt. Wear chemical resistant gloves during mixing and loading, equipment repair and cleaning, and during reentry to treated areas before the reentry interval has expired.

Important! Before removing gloves, wash them with soad and water. Always wash hands, face, and arms with soap and water before smoking, drinking, eating or toileting."

V. PRODUCTS SUBJECT TO THIS STANDARD

All products containing one or more of the pesticides identified in Section II.A. are subject to certain requirements for data submission or changes in composition, labeling or packaging of the product. The applicable requirements depend on whether the product is a manufacturing or end use product and whether the pesticide is the sole active ingredient or one of multiple active ingredients.

Products are subject to this Registration Standard as follows:

A. Manufacturing use products containing this pesticide as the sole active ingredient are subject to:

1. The restrictions (if any) upon use, composition, or packaging listed in Section IV, if they pertain to the manufacturing use product.

2. The data requirements listed in Tables A and B[2]

3. The labeling requirements specified for manufacturing use products in Section IV.

4. Administrative requirements (application forms, Confidential Statement of Formula, data compensation provisions) associated with reregistration.

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[2] Data requirements are listed in the three Tables in Appendix I of this Registration Standard. The Guide to Tables in that Appendix explains how to read the Tables.

Table A lists generic data requirements applicable to all products containing the pesticide subject to this Registration Standard. Table B lists product-specific data applicable to manufacturing use products. The data in Tables A and B need not be submitted by a producer who is eligible for the formulator's exemption for that active ingredient.

Table C lists product-specific data applicable to end use products. The Agency has decided that, in most cases, it will not require the submission of product-specific data for end use products at this time. Therefore most Registration Standards do not contain a Table C.

B. Manufacturing use products containing this pesticide as one of multiple active ingredients are subject to:

The data requirements listed in Table A and label requirements.

C. End use products containing this pesticide as the sole active ingredient* are subject to:

1. The restrictions (if any) upon use, composition, or packaging listed in Section IV if they pertain to the end use product.

2. If eligible for the formulator's exemption[3], the data requirements listed in Table C.

3. If not eligible for the formulator's exemption, the data requirements listed in Table A and the data requirements listed in Table C.

4. The labeling requirements specified for end use products in Section IV.

D. End use products containing this pesticide as one of multiple active ingredients are subject to:

a. If not eligible for the formulator's exemption, the date requirements listed in Tables A and C.

b. If eligible for the formulator's exemption, the data requirements listed in Table C.

c. Labeling requirements specified for end use products.

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[3] If you purchase from another producer and use as the source of your active ingredient only EPA-registered products, you are eligible for the formulator's exemption for generic data concerning that active ingredient (Table A) and product-specific data for the registered manufacturing use product you purchase (Table B).

Two circumstances nullify this exemption:

1) If you change sources of active ingredient to an unregistered product, formulate your own active ingredient, or acquire your active ingredient from a firm with ownership in common with yours, you individually lose the exemption and become subject to the data requirements in Table A.

2) If no producer subject to the generic data requirements in Table A agrees to submit the required data, all end use producers lose the exemption, and become subject to those data requirements.

* Solvents or diluents must be declared as inerts. The Agency does not have data indicating that these solvents are insecticidal.

VI. REQUIREMENT FOR SUBMISSION OF GENERIC DATA

This portion of the Registration Standard is a notice issued under the authority of FIFRA sec. 3(c)(2)(B). It refers to the data listed in Table A, which are required to be submitted by registrants to maintain in effect the registration of products containing this active ingredient.[4]

A. What are generic data?

Generic data pertain to the properties or effects of a particular active ingredient. Such data are relevant to an evaluation of all products containing that active ingredient regardless of whether the product contains other ingredients. (unless the product bears labeling that would make the data requirement inapplicable).

Generic data may also be data on a "typical formulation" of a product. "Typical formulation" testing is often required for ecological effects studies and applies to all products having that formulation type. These are classed as generic data, and are contained in Table A.

B. Who must submit generic data?

All current registrants are responsible for submitting generic data in response to a data request under FIFRA sec. 3(c)(2)(B) (DCI Notice). EPA has decided, however, not to require a registrant who qualifies for the formulator's exemption (FIFRA sec. 3(c)(2)(D) and § 152.85) to submit generic data in response to a DCI notice if the registrant who supplies the active ingredient in his product is complying with the data request.

If you are not now eligible for a formulator's exemption, you may qualify for one if you change your source of supply to a registered source that does not share ownership in common with your firm. If you choose to change sources of supply, the Confidential Statement of Formula must identify the new source(s) and you must submit a Formulator's Exemption Statement form.

If you apply for a new registration for products containing this active ingredient after the issuance of this Registration Standard, you will be required to submit or cite generic data relevant to the uses of your product if, at the time the application is submitted, the data have been submitted to the Agency by current registrants. If the required data have not yet been submitted, any new registration will be conditioned upon the new registrant's submission or citation of the required data not later than the date upon which current registrants of similar products are required to provide such data. See FIFRA sec. 3(c)(7)(A). If you thereafter fail to comply with the condition of that registration to provide data, the registration may be cancelled (FIFRA sec. 6(e)).

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[4] Registrations granted after issuance of this Standard will be conditioned upon submission or citation of the data listed in this Registration Standard.

C. What generic data must be submitted?

You may determine which generic data you must submit by consulting Table A. That table lists the generic data needed to evaluate current uses of all products containing this active ingredient, the uses for which such data are required, and the dates by which the data must be submitted to the Agency.

D. How to comply with DCI requirements.

Within 90 days of your receipt of this Registration Standard, you must submit to EPA a completed copy of the form entitled "FIFRA Section 3(c)(2)(B) Summary Sheet" (EPA Form 8580-1, enclosed) for each of your products. On that form you must state which of the following six methods you will use to comply with the DCI requirements:

1. You will submit the data yourself.

2. You have entered into an agreement with one or more registrants to jointly develop (or share in the cost of developing) the data, but will not be submitting the data yourself. If you use this method, you must state who will submit the data on which you will rely. You must also provide EPA with documentary evidence that an agreement has been formed which allows you to rely upon the data to be submitted. Such evidence may be: (1) your letter offering to join in an agreement and the other registrant's acceptance of your offer, (2) a written statement by the parties that an agreement exists, or (3) a written statement by the person who will be submitting the data that you may rely upon its submission. The Agency will also require adequate assurance that the person whom you state will provide the data is taking appropriate steps to secure it. The agreement to produce the data need not specify all of the terms of the final arrangement between the parties or a mechanism to resolve the terms.

3. You have attempted to enter into an agreement to jointly develop data, but no other registrant has accepted your offer. You request that EPA not suspend your registration for non-compliance with the DCI. EPA has determined that, as a general policy, it will not suspend the registration of a product when the registrant has in good faith sought and continues to seek to enter into a data development/cost sharing program, but the other registrants developing the data have refused to accept its offer. [If your offer is accepted, you may qualify for Option 2 above by entering into an agreement to supply the data.]

In order to qualify for this method, you must:

1. File with EPA a completed "Certification of Attempt to Enter into an Agreement with other Registrants for Development of Data" (EPA Form 8580-6, enclosed).

2. Provide us with a copy of your offer to the other registrant and proof of the other registrant's receipt of your offer (such as a certified mail receipt). Your offer must, at a minimum, contain the following language or its equivalent:

> [Your company name] offers to share in the burden of producing the data required pursuant to FIFRA sec. 3(c)(2)(B) in the [name of active ingredient] Registration Standard upon terms to be agreed or failing agreement to be bound by binding arbitration as provided by FIFRA section 3(c)(2)(B)(iii).

The remainder of your offer may not in any way attempt to limit this commitment. If the other registrant to whom your offer is made does not accept your offer, and if the other registrant informs us on a DCI Summary Sheet that he will develop and submit the data required under the DCI, then you may qualify for this option. In order for you to avoid suspension under this method, you may not later withdraw or limit your offer to share in the burden of developing the data. In addition, the other registrant must fulfill its commitment to develop and submit the data.

4. You request a waiver of the data requirement. If you believe that a data requirement does not (or should not) apply to your product or its uses, you must provide EPA with a statement of the reasons why you believe this is so. Your statement must address the specific composition or use factors that lead you to believe that a requirement does not apply. Since the Agency has carefully considered the composition and uses of pesticide products in determining that a data requirement applies, EPA does not anticipate that many waivers will be granted. A request for waiver does not extend the timeframes for developing required data, and if your waiver request is denied, your registration may be suspended if you fail to submit the data.

5. You request that EPA amend your registration by deleting the uses for which the data are needed. You are not required to submit data for uses which are no longer on your label.

6. You request voluntary cancellation of the registration of your product(s) for which the data are needed.

E. Procedures for requesting a change in testing protocol.

If you will generate the required data and plan to use test procedures which deviate from (or are not specified in) either EPA's Pesticide Assessment Guidelines or the Reports of Expert Groups to the Chemicals Group, Organization for Economic Cooperation and Development (OECD) Chemicals Testing Programme, you must submit for EPA approval the protocols you propose to use.

You should submit your protocols before beginning testing and await EPA approval, because the Agency will not ordinarily accept as sufficient studies using unapproved protocols. A request for protocol approval will not extend the timeframe for submission of the data, nor will extensions generally be given to conduct studies due to submittal of inappropriate protocols.

F. Procedures for requesting extensions of time.

If you think that you will need more time to generate the data than is allowed by EPA's schedule, you may submit a request for an extension of time. Any request for a time extension which is made as an initial response to a section 3(c)(2)(B) request notice must be submitted in writing to the Product Manager listed at the end of this section and must be made before the deadline for response. Once dates have been committed to and EPA has accepted these commitments, any subsequent requests for a time extension must be submitted in writing to the Office of Compliance Monitoring.

EPA will view failure to request an extension before the response deadline as a waiver of any future claim that there was insufficient time to submit the data. While EPA considers your request, you must strive to meet the deadline for submitting the data.

The extension request should state the reasons why you believe that an extension is necessary and the steps you have taken to meet the testing deadline. Time extensions normally will not be granted due to problems with laboratory capacity or adequacy of funding, since the Agency believes that with proper planning these can be overcome. Time extensions may be considered when joint data development is planned, or when the Agency must approve a new or modified protocol before the study can be begun.

A request for an extension does not extend the timeframe for submission of the data. If EPA denies your request for a time extension and you do not submit the data as requested, EPA may begin proceedings to suspend the registrations of your products.

G. Existing stocks provision upon suspension or cancellation.

The Agency has determined that if a registration is suspended for failure to respond to a DCI request under FIFRA sec. 3(c)(2)(B), an existing stocks provision is not consistent with the Act. Accordingly, the Agency does not anticipate granting permission to sell or distribute existing stocks of suspended product except in rare circumstances. If you believe that your product will be suspended or cancelled and that an existing stocks provision should be granted, you have the burden of clearly demonstrating to EPA that granting such permission would be consistent with the Act. The following information must be included in any request for an existing stocks provision:

1. Explanation of why an existing stocks provision is necessary, including a statement of the quantity of existing stocks and your estimate of the time required for their sale or distribution; and

2. Demonstration that such a provision would be consistent with the provisions of FIFRA.

VII. REQUIREMENT FOR SUBMISSION OF PRODUCT-SPECIFIC DATA

Under its DCI authority, EPA has determined that certain product-specific data are required to maintain your registrations in effect. Product-specific data are derived from testing using a specific formulated product, and, unlike generic data, generally support only the registration of that product. All such data must be submitted by the dates specified in this Registration Standard.

If you have a manufacturing use product, these data are listed in Table B. If you have an end use product, the data are listed in Table C. As noted earlier, the Agency has decided that it will not routinely require product-specific data for end use products at this time. Therefore, Table C may not be contained in this Registration Standard; if there is no Table C, you are not required to submit the data at this time.

In order to comply with the product specific data requirements, you must follow the same procedures as for generic data. See Section IV.D, E, F, and G. You should note, however, that product chemistry data are required for every product, and the only acceptable responses are options IV.D.1. (submit data) or IV.D.6.(cancellation of registration).

Failure to comply with the product-specific data requirements for your products will result in suspension of the product's registration.

VIII. REQUIREMENT FOR SUBMISSION OF REVISED LABELING

FIFRA requires each product to be labeled with accurate, complete and sufficient instructions and precautions, reflecting the Agency's assessment of the data supporting the product and its uses. General labeling requirements are set out in 40 CFR 162.10 (see Appendix II - LABELING and SUMMARY). In addition, labeling requirements specific to products containing this pesticide are specified in Section IV.D of this Registration Standard. Applications submitted in response to this notice must include draft labeling for Agency review.

If you fail to submit revised labeling as required, which complies with 40 CFR 162.10 and the specific instructions in Section IV.D., EPA may seek to cancel or suspend the registration of your product under FIFRA sec. 6.

IX. INSTRUCTIONS FOR SUBMISSION

A. Manufacturing Use Products (MUPs) containing azinphos-methyl as sole active ingredient.

1. Within 90 days from receipt of this document, you must submit to the Product Manager in the Registration Division for each product subject to this Registration Standard:

a. The "FIFRA Section 3(c)(2)(B) Summary Sheet" (EPA Form 8580-1), with appropriate attachments.[5]

b. Confidential Statement of Formula (EPA Form 8570-4).

c. Formulator's Exemption Statement (EPA Form), if applicable.

d. Evidence of compliance with data compensation requirements of FIFRA sec. 3(c)(1)(D). Refer to 40 CFR 152.80-152.99.

2. Within 9 months from receipt of this document you must submit to the Product Manager:

a. Application for Pesticide Registration (EPA Form 8570-1).

b. Two copies of any required product-specific data (See Table B).

c. Three copies of draft labeling, including the container label and any associated supplemental labeling. Labeling should be either typewritten text on 8-1/2 x 11 inch paper or a mockup of the labeling suitable for storage in 8-1/2 x 11 files. The draft label must indicate the intended colors of the final label, clear indication of the front panel of the label, and the intended type sizes of the text.

d. Product Specific Data Report (EPA Form 8580-4).

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[5] If on the Summary Sheet, you commit to develop the data, present arguments that a data requirement is not applicable or should be waived, or submit protocols or modified protocols for Agency review, you must submit a copy of the Summary Sheet (and any supporting information) to the Office of Compliance Monitoring, which will be monitoring the data generated in response to this notice. This submission is in addition to responding to the Product Manager, and should be submitted to the Office of Compliance Monitoring at the address given at the end of this section. (Actual studies are not to be submitted to the Office of Compliance Monitoring.)

3. Within the times set forth in Table A, you must submit to the Registration Division all generic data, unless you are eligible for the formulator's exemption. If for any reason any test is delayed or aborted so that the schedule cannot be met, immediately notify the Product Manager and the Office of Compliance Monitoring of the problem, the reasons for the problem, and your proposed course of action.

B. Manufacturing Use Products containing azinphos-methyl in combination with other active ingredients.

1. Within 90 days from receipt of this document, you must submit to the Product Manager in the Registration Division:

a. FIFRA sec. 3(c)(2)(B) Summary Sheet, with appropriate attachments[5] (EPA Form 8580-1).

b. Confidential Statement of Formula (EPA Form 8570-4)

c. Formulator's Exemption Statement, if applicable.

2. Within the time frames set forth in Table A, you must submit to the Registration Division all generic data, unless you are eligible for the formulator's exemption. If for any reason any test is delayed or aborted so that the schedule cannot be met, immediately notify the Product Manager and the Office of Compliance Monitoring of the problem, the reasons for the problem, and your proposed course of action.

C. End Use Products containing azinphos-methyl as sole active and multiple active ingredient.

1. Within 90 days from receipt of this document, you must submit to the Product Manager in the Registration Division:

a. FIFRA Section 3(c)(2)(B) Summary Sheet, with appropriate attachments[5] (EPA Form 8580-1).

b. Confidential Statement of Formula (EPA Form 8570-4).

c. Formulator's Exemption Statement if applicable.

2. Within 9 months from receipt of this document you must submit to the Product Manager:

a. Two copies of any product-specific data, if required by Table C.

b. Product Specific Data Report (EPA Form 8580-4), if Table C lists required product-specific data.

c. Three copies of draft labeling, including the container label and any associated supplemental labeling. Labeling should be either typewritten text on 8-1/2 x 11 inch paper or a mockup of the labeling suitable for storage in 8-1/2 x 11 files. The draft labeling must indicate the intended colors of the final label, clear indication of the front panel of the label, and the intended type sizes of the text. End use product labeling must comply specifically with the instructions in Section IV (Regulatory Position and Rationale).

D. Intrastate Products containing azinphos-methyl either as sole active ingredient or in combination with other active ingredients.

These products are being called in for full Federal registration. Producers of these products are being sent a letter instructing them how to submit an application for registration.

E. Addresses

The required information must be submitted to the following address:

Lawrence J. Schnaubelt
Registration Division (TS-767C)
Office of Pesticide Programs
Environmental Protection Agency
401 M St., SW
Washington, D.C. 20460

The address for submissions to the Office of Compliance Monitoring is:

Laboratory Data Integrity Program
Office of Compliance Monitoring (EN-342)
Environmental Protection Agency
401 M St., SW
Washington, D.C. 20460.

TGUIDE-1

GUIDE TO TABLES

Tables A, B, and C contain listings of data requirements for the pesticides covered by this Registration Standard.

Table A contains generic data requirements that apply to the pesticide in all products, including data requirements for which a "typical formulation" is the test substance.

Table B contains product-specific data requirements that apply only to a manufacturing use product.

Table C contains product-specific data requirements that apply only to an end use product.

The data tables are generally organized according to the following format:

1. Data Requirement (Column 1). The data requirements are listed in the order in which they appear in 40 CFR Part 158. The reference numbers accompanying each test refer to the test protocols set out in the Pesticide Assessment Guidelines, which are available from the National Technical Information Service, 5285 Port Royal Road, Springfield, VA 22161.

2. Test Substance (Column 2). This column lists the composition of the test substance required to be used for the test, as follows:

TGAI = Technical grade of the active ingredient
PAI = Pure active ingredient
PAIRA = Pure active ingredient, radio labeled
TEP = Typical end use formulation
MP = Manufacturing use product
EP = End use product

Any other test substances, such as metabolites, will be specifically named in Column 2 or in footnotes to the table.

3. Use pattern (Column 3). This column indicates the use patterns to which the data requirement applies. Use patterns are the same as those given in 40 CFR Part 158. The following letter designations are used for the given use patterns:

A = Terrestrial, food
B = Terrestrial, non-food
C = Aquatic, food
D = Aquatic, non-food
E = Greenhouse, food
F = Greenhouse, non-food
G = Forestry
H = Domestic outdoor
I = Indoor

Any other designations will be defined in a footnote to the table.

4. Does EPA have data? (Column 4). This column indicates one of three answers:

> YES - EPA has data in its files that completely satisfy this data requirement. These data may be cited by other registrants in accordance with data compensation requirements of Part 152, Subpart E.
>
> PARTIALLY - EPA has some data in its files, but such data do not fully satisfy the data requirement. In some cases, the Agency may possess data on one of two required species, or may possess data on one test substance but not all. The term may also indicate that the data available to EPA are incomplete. In this case, when the data are clarified, or additional details of the testing submitted by the original data submitter, the data may be determined to be acceptable. If this is the case, a footnote to the table will usually say so.
>
> NO - EPA either possesses no data which are sufficient to fulfill the data requirement, or the data which EPA does possess are flawed scientifically in a manner that cannot be remedied by clarification or additional information.

5. Bibliographic citation (Column 5). If the Agency has acceptable data in its files, this column lists the identifying number of each study. This normally is the Master Record Identification (MRID) number, but may be a GS number if no MRID number has been assigned. Refer to the Bibliography Appendices for a complete citation of the study.

6. Must additional data be submitted? (Column 6). This column indicates whether the data must be submitted to the Agency. If column 3 indicates that the Agency already has data, this column will usually indicate NO. If column 3 indicates that the Agency has only partial data or no data, this column will usually indicate YES. In some cases, even though the Agency does not have the data, EPA will not require its submission because of the unique characteristics of the chemical; because data on another chemical can be used to fulfill the data requirement; or because the data requirement has been waived or reserved. Any such unusual situations will be explained in a footnote to the table.

7. Timeframe for submission (Column 7). If column 5 requires that data be submitted, this column indicates when the data are to be submitted, based on the issuance date of the Registration Standard. The timeframes are those established either as a result of a previous Data Call-In letter, or standardized timeframes established by PR Notice 85-5 (August 22, 1985).

8. Footnotes (at the end of each table). Self-explanatory.

TABLE A
GENERIC DATA REQUIREMENTS FOR AZINPHOS-METHYL

Data Requirement	Test Substance	Use Patterns	Does EPA Have Data? 1/	Bibliographic Citation	Must Additional Data be Submitted? 2/	Time Frame for Submission
§158.120 Product Chemistry						
Product Identity						
61-2 - Description of Beginning Materials and Manufacturing Process	TGAI	All	No	-	Yes 2/	6 Months
61-3 - Discussion of Formation of Impurities	TGAI	All	No	-	Yes 2/	6 Months
Analysis and Certification of Product Ingredients						
62-1 - Preliminary Analysis	TGAI	All	No	-	Yes 2/	12 Months
Physical and Chemical Characteristics						
63-2 - Color	TGAI	All	No	-	Yes 2/	6 Months
63-3 - Physical State	TGAI	All	No	-	Yes 2/	6 Months
63-4 - Odor	TGAI	All	No	-	Yes 2/	6 Months
63-5 - Melting Point	TGAI	All	No	-	Yes 2/	6 Months
63-6 - Boiling Point	TGAI	All	No	-	Yes 2/	6 Months

TABLE A
GENERIC DATA REQUIREMENTS FOR AZINPHOS-METHYL

Data Requirement	Test Substance	Use Patterns	Does EPA Have Data? 1/	Bibliographic Citation	Must Additional Data be Submitted? 2/	Time Frame for Submission
§158.120 Product Chemistry (Continued)						
Physical and Chemical Characteristics (Continued)						
63-7 - Density, Bulk Density, or Specific Gravity	TGAI	All	No	-	Yes 2/	6 Months
63-8 - Solubility	TGAI or PAI	All	No	-	Yes 2/	6 Months
63-9 - Vapor Pressure	PAI	All	No	-	Yes 2/	6 Months
63-10 - Dissociation constant	PAI	All	No	-	Yes 2/	6 Months
63-11 - Octanol/water partition coefficient	PAI	All	No	-	Yes 2/	6 Months
63-12 - pH	TGAI	All	No	-	Yes 2/	6 Months
63-13 - Storage Stability	TGAI	All	No	-	Yes 2/	15 Months

1/ Although product chemistry data may have been submitted in the past, the Agency has determined that these data must be resubmitted for each pesticide. New requirements have been introduced and previously submitted data must be updated. Therefore bibliographic citations for the old data are not applicable.

2/ Generic data are required for the following technical formulations : EPA REG. NO. 3125-108, EPA REG. NO. 11678-4, EPA REG. NO. 2749-291,and EPA REG. NO. 10163-95.

TABLE A
GENERIC DATA REQUIREMENTS FOR AZINPHOS-METHYL

Data Requirement	Test Substance	Does EPA Have Data?	Bibliographic Citation	Must Additional Data be Submitted?	Timeframe for Submission
§158.125 Residue Chemistry					
171-4 - Nature of Residue (Metabolism)					
- Plants	PAIRA	Partially	00100826 00107018 00112112 GS0235008 00155026 00155065	Yes 1/	18 Months
- Livestock	PAIRA and Plant Metabolites	Partially	00090275 00090278 00155021 00155019 00155020	Yes 2/	18 Months
171-4 - Residue Analytical Method					
- Plant residues	TGAI & Metabolites	Yes	00080102 00089642 00089740 00090126 00090127 00090277 00090279 00090946 00093572 00106832 00107018 00107020	No 3/	

TABLE A
GENERIC DATA REQUIREMENTS FOR AZINPHOS-METHYL

Data Requirement	Test Substance	Does EPA Have Data?	Bibliographic Citation	Must Additional Data be Submitted?	Timeframe for Submission
171-4 - Residue Analytical Method (cont'd)					
- Plant residues (cont'd)			00112052 00112054 00112074 00112083 00112114 00112116 00112120 00112145 00141541 05004211 00155064 00158905 00158906 00112093		
- Animal residues	TGAI & Metabolites	Yes	00030303 00090274 05004211 GS0235014 GS0235015	No 3/	

TABLE A
GENERIC DATA REQUIREMENTS FOR AZINPHOS-METHYL

Data Requirement	Test Substance	Does EPA Have Data?	Bibliographic Citation	Must Additional Data be Submitted?	Timeframe for Submission
§158.125 Residue Chemistry - Continued					
171-4 - Residue Analytical Method (cont'd)					
- Storage Stability Data	PAI	Partially	00030303 00090127 00090275 00112078 00155064	Yes 4/	15 Months
171-4 - Magnitude of the Residue-Residue Studies for Each Food Use					
- Root and Tuber Vegetables Group 5/					
o Crop - Potatoes					
-- Crop field trials	TEP	Yes	00112039 00112053	No 6/	
— Processed Food/Feed	EP	Partially	00154989	Yes 7/	24 Months
- Bulb Vegetable Group 8/					
o Crop - Onions					
-- Crop field trials	TEP	Partially	00112111	Yes 9/	18 Months

TABLE A
GENERIC DATA REQUIREMENTS FOR AZINPHOS-METHYL

Data Requirement	Test Substance	Does EPA Have Data?	Bibliographic Citation	Must Additional Data be Submitted?	Timeframe for Submission
§158.125 Residue Chemistry - Continued					
171-4 - Magnitude of the Residue-Residue Studies for Each Food Use					
- Leafy Vegetables Group 10/					
o Crop - Celery					
— Crop field trials	TEP	Partially	00107018	Yes 11/	18 Months
o Crop - Parsley					
— Crop field trials	TEP	Yes	00112073	No	
o Crop - Spinach					
— Crop field trials	TEP	Partially	0089740	Yes 12/	18 Months
- Brassica Leafy Vegetable Group 13/					
o Crop - Broccoli					
— Crop field trials	TEP	Partially	00080143 00080144 00107020 00112116 00154989	Yes 14/	18 Months

TABLE A
GENERIC DATA REQUIREMENTS FOR AZINPHOS-METHYL

Data Requirement	Test Substance	Does EPA Have Data?	Bibliographic Citation	Must Additional Data be Submitted?	Timeframe for Submission
§158.125 Residue Chemistry - Continued					
171-4 - Magnitude of the Residue-Residue Studies for Each Food Use					
o Crop - Brussels Sprouts					
-- Crop field trials	TEP	Partially	00090127 00154989	Yes 15/	18 Months
o Crop - Cabbage					
-- Crop field trials	TEP	Partially	00112116 00107020	Yes 16/	18 Months
o Crop - Cauliflower					
— Crop field trials	TEP	Partially	00112116 00107020	Yes 17/	18 Months
- Legume Vegetables Group 18/					
o Crop - Beans (Dry and Snap)					
-- Crop field trials	TEP	Partially	00087512 00089740 00090946 00107019 00112052 00154989	Yes 19/	18 Months

TABLE A
GENERIC DATA REQUIREMENTS FOR AZINPHOS-METHYL

Data Requirement	Test Substance	Does EPA Have Data?	Bibliographic Citation	Must Additional Data be Submitted?	Timeframe for Submission
§158.125 Residue Chemistry - Continued					
171-4 - Magnitude of the Residue-Residue Studies for Each Food Use					
o Crop - Peas					
-- Crop field trials	TEP	Partially	00107019 00112035 00112052	Yes 20/	18 Months
o Crop - Soybeans					
-- Crop field trials	TEP	Partially	00107020 00112039 00112052 00112086 00112151	Yes 21/	18 Months
-- Processed Food/Feed	EP	No	-	Yes 22/	24 Months
- Fruiting Vegetable Group 23/					
o Crop - Eggplants					
-- Crop field trials	TEP	No	-	Yes 24/	18 Months
o Crop - Peppers					
-- Crop field trials	TEP	Partially	00107020	Yes 25/	18 Months

TABLE A
GENERIC DATA REQUIREMENTS FOR AZINPHOS-METHYL

Data Requirement	Test Substance	Does EPA Have Data?	Bibliographic Citation	Must Additional Data be Submitted?	Timeframe for Submission
§158.125 Residue Chemistry - Continued					
171-4 - Magnitude of the Residue-Residue Studies for Each Food Use					
o Crop - Tomatoes					
— Crop field trials	TEP	Partially	00080143 00089740 00112120 00154996 00154989	Yes 26/	18 Months
-- Processed Food/Feed	EP	No	-	Yes 27/	24 Months
- Cucurbit Vegetables Group 28/					
o Crop - Cucumbers					
-- Crop field trials	TEP	Partially	00107019	Yes 29/	18 Months
o Crop - Melons					
— Crop field trials	TEP	Partially	00107018	Yes 30/	18 Months
- Citrus Fruits Group					
— Crop field trials	TEP	Partially	00090126 00106832 00112037 00112139 00112143 00112145	Yes 31/	18 Months

TABLE A
GENERIC DATA REQUIREMENTS FOR AZINPHOS-METHYL

Data Requirement	Test Substance	Does EPA Have Data?	Bibliographic Citation	Must Additional Data be Submitted?	Timeframe for Submission
§158.125 Residue Chemistry - Continued					
171-4 - Magnitude of the Residue-Residue Studies for Each Food Use					
- Citrus Fruits Group					
-- Processed Food/Feed	EP	Partially	00112037 00090126 00112143	Yes 32/	24 Months
- Pome Fruits Group 33/					
o Crop - Apples					
-- Crop field trials	TEP	Partially	00087512 00100824 00112113 00112137 00154989	Yes 34/	18 Months
-- Processed Food/Feed	EP	Partially	00154989 00100824	Yes 35/	24 Months
o Crop - Crabapples					
— Crop field trials	TEP	No	-	No 36/	

TABLE A
GENERIC DATA REQUIREMENTS FOR AZINPHOS-METHYL

Data Requirement	Test Substance	Does EPA Have Data?	Bibliographic Citation	Must Additional Data be Submitted?	Timeframe for Submission
§158.125 Residue Chemistry - Continued					
171-4 - Magnitude of the Residue-Residue Studies for Each Food Use					
o Crop - Pears					
-- Crop field trials	TEP	Yes	00087512 00100824 00155064 00154989	No 36/	
o Crop - Quinces	TEP	No	-	No 36/	
- Stone Fruits Crop 37/					
o Crop - Apricots					
-- Crop field trials	TEP	Partially	00100824 00154989	Yes 38/	18 Months
o Crop - Cherries					
-- Crop field trials	TEP	Partially	00107020 00112145 00154989	Yes 39/	18 Months
o Crop - Nectarines					
-- Crop field trials	TEP	Partially	00154989	Yes 40/	18 Months

TABLE A
GENERIC DATA REQUIREMENTS FOR AZINPHOS-METHYL

Data Requirement	Test Substance	Does EPA Have Data?	Bibliographic Citation	Must Additional Data be Submitted?	Timeframe for Submission
§158.125 Residue Chemistry - Continued					
171-4 - Magnitude of the Residue-Residue Studies for Each Food Use					
o Crop - Peaches					
-- Crop field trials	TEP	Partially	00100824 00154989	Yes 41/	18 Months
o Crop - Plums					
-- Crop field trials	TEP	Partially	00107020 00154989	Yes 42/	18 Months
-- Processed Food/Feed	EP	No	-	Yes 43/	24 Months
- Small Fruits and Berries Group 44/					
o Crop - Blackberries					
-- Crop field trials	TEP	Partially	00089890 00112143	Yes 45/	18 Months
o Crop - Blueberries					
-- Crop field trials	TEP	Partially	00089740 00107018 00112143	Yes 46/	18 Months

TABLE A
GENERIC DATA REQUIREMENTS FOR AZINPHOS-METHYL

Data Requirement	Test Substance	Does EPA Have Data?	Bibliographic Citation	Must Additional Data be Submitted?	Timeframe for Submission
§158.125 Residue Chemistry - Continued					
171-4 - Magnitude of the Residue-Residue Studies for Each Food Use					
o Crop - Boysenberries					
-- Crop field trials	TEP	Partially	00089890	No 47/	
o Crop - Cranberries					
-- Crop field trials	TEP	Partially	00089740	Yes 48/	18 Months
o Crop - Gooseberries 49/					
o Crop - Grapes					
-- Crop field trials	TEP	Partially	00089642 00112108 00112143 00154989	Yes 50/	18 Months
-- Processed Food/Feed	EP	Partially	00089642 00112108 00112143 00154989	Yes 51/	24 Months
o Crop - Loganberries					
-- Crop field trials	TEP	Yes	00089890	No 52/	

TABLE A
GENERIC DATA REQUIREMENTS FOR AZINPHOS-METHYL

Data Requirement	Test Substance	Does EPA Have Data?	Bibliographic Citation	Must Additional Data be Submitted?	Timeframe for Submission
§158.125 Residue Chemistry - Continued					
171-4 - Magnitude of the Residue-Residue Studies for Each Food Use					
o Crop - Raspberries					
-- Crop field trials	TEP	Yes	00089890 00112142	No 52/	
o Crop - Strawberries					
— Crop field trials	TEP	Partially	00107020	Yes 53/	18 Months
- Tree Nuts Group 54/					
o Crop - Almonds					
-- Crop field trials	TEP	Partially	00109278 00112159 00158908	Yes 55/	18 Months
o Crop - Filberts					
— Crop field trials	TEP	Partially	00089740 00112117	Yes 56/	18 Months
o Crop - Pecans					
-- Crop field trials	TEP	Partially	00112126	Yes 57/	18 Months

TABLE A
GENERIC DATA REQUIREMENTS FOR AZINPHOS-METHYL

Data Requirement	Test Substance	Does EPA Have Data?	Bibliographic Citation	Must Additional Data be Submitted?	Timeframe for Submission
§158.125 Residue Chemistry - Continued					
171-4 - Magnitude of the Residue-Residue Studies for Each Food Use					
o Crop - Walnuts					
-- Crop field trials	TEP	Partially	00112052	Yes 58/	18 Months
- Cereal Grains Group 59/					
o Crop - Barley Grain					
-- Crop field trails	TEP	Yes	00093570 00093572	No 60/	
o Crop - Oat Grain					
-- Crop field trials	TEP	Yes	00093570 00093572	No 60/	
o Crop - Rye Grain					
-- Crop field trials	TEP	Yes	00093572	No 60/	
o Crop - Wheat grain					
-- Crop field trials	TEP	Partially	00080143 00080144 00093570 00093572 00154989	Yes 61/	18 Months
-- Processed Food/Feed	EP	No	-	Yes 62/	24 Months

TABLE A
GENERIC DATA REQUIREMENTS FOR AZINPHOS-METHYL

Data Requirement	Test Substance 1/	Does EPA Have Data?	Bibliographic Citation	Must Additional Data be Submitted?	Timeframe 2/ for Submission
§158.125 Residue Chemistry - Continued					
171-4 - Magnitude of the Residue-Residue Studies for Each Food Use					
- Forage, Fodder, and Straw of Cereal Grains Group 63/					
o Crop - Barley, Forage, Hay and Straw					
-- Crop field trials	TEP	Yes	00093570 00093572	No 64/	
o Crop - Oat, Forage, Hay, and Straw					
-- Crop field trials	TEP	Yes	00093570 00093572	No 64/	
o Crop - Rye Straw					
— Crop field trials	TEP	Yes	00093572	No 64/	
o Crop - Wheat Forage, Hay, and Straw					
-- Crop field trials	TEP	Partially	00080143 00080144 00093570 00093572 00154989	Yes 65/	18 Months

TABLE A
GENERIC DATA REQUIREMENTS FOR AZINPHOS-METHYL

Data Requirement	Test Substance	Does EPA Have Data?	Bibliographic Citation	Must Additional Data be Submitted?	Timeframe for Submission
§158.125 Residue Chemistry - Continued					
171-4 - Magnitude of the Residue-Residue Studies for Each Food Use					
- Grass Forage, Fodder, and Hay 66/					
o Crop - Grass Forage, and Hay					
-- Crop field trials	TEP	Partially	00070492 00112035 00117750	Yes 67/	18 Months
- Non-Grass Animal Feeds Group 68/					
o Crop - Alfalfa Forage and Hay					
-- Crop field trials	TEP	Partially	00035890 00067494 00090273 00090276 00090280 00154989	Yes 69/	18 Months
o Crop - Birdsfoot Trefoil Forage and Hay					
-- Crop field trials	TEP	No	-	No 70/	

TABLE A
GENERIC DATA REQUIREMENTS FOR AZINPHOS-METHYL

Data Requirement	Test Substance	Does EPA Have Data?	Bibliographic Citation	Must Additional Data be Submitted?	Timeframe for Submission
§158.125 Residue Chemistry - Continued					
171-4 - Magnitude of the Residue-Residue Studies for Each Food Use					
o Crop - Clover Forage and Hay					
-- Crop field trials	TEP	Partially	00090273 00090280	Yes 71/	18 Months
- Miscellaneous Commodities					
o Crop - Artichokes					
-- Crop field trials	TEP	Partially	00089740	Yes 72/	18 Months
o Crop - Cottonseed					
-- Crop field trials	TEP	Partially	00029078 00045038 00080143 00080144 00087511 00098957 00102272 00102299 00112027 00112039 00112054 00112071 00112110 00112112	Yes 73/	18 Months

TABLE A
GENERIC DATA REQUIREMENTS FOR AZINPHOS-METHYL

Data Requirement	Test Substance	Does EPA Have Data?	Bibliographic Citation	Must Additional Data be Submitted?	Timeframe for Submission
§158.125 Residue Chemistry - Continued					
171-4 - Magnitude of the Residue-Residue Studies for Each Food Use					
o Crop - Cottonseed (cont'd)					
-- Crop field trials			00112114 00141541 00154989		
-- Processed Food/Feed	EP	Partially	00102272 00112039 00112054 00112112 00112071	Yes 74/	24 Months
o Crop - Kiwi					
-- Crop field trials	TEP	Partially	00112072 00158909	Yes 75/	18 Months
o Crop - Pistachio					
-- Crop field trials	TEP	Yes	00112074	No	
o Crop - Sugarcane					
-- Crop field trials	TEP	Partially	00091562 00112024 00112026 00112083 00112115	Yes 76/	18 Months

TABLE A
GENERIC DATA REQUIREMENTS FOR AZINPHOS-METHYL

Data Requirement	Test Substance	Does EPA Have Data?	Bibliographic Citation	Must Additional Data be Submitted?	Timeframe for Submission
§158.125 Residue Chemistry - Continued					
171-4 - Magnitude of the Residue-Residue Studies for Each Food Use					
o Crop - Tobacco					
— Crop field trials	TEP	No	-	Yes 77/	18 Months
- Magnitude of the Residue in Meat, Milk, Poultry, and Eggs					
o Cattle, Goats, Sheep, and Horses	TEP	Yes	00030303 00090126	No 78/	
o Milk		Yes	00030303 00090126	No 78/	

TABLE A
GENERIC DATA REQUIREMENTS FOR AZINPHOS-METHYL

§158.125 Residue Chemistry - Footnotes

1/ The metabolism of azinphos-methyl in plants is not adequately understood. Data reflecting the distribution and metabolism of either benzene or triazine-labeled [^{14}C]azinphos-methyl in mature fruit of an orchard crop, mature cottonseed, and mature potato tubers following foliar treatment are required. Application rates must be sufficiently high to permit complete ^{14}C-residue identification.

2/ Metabolism studies utilizing ruminants and poultry are required. Animals must be dosed for three days with ring-labeled [^{14}C]azinphos-methyl at a level sufficient to make residue identification and quantification possible. Milk and eggs must be collected twice daily during the dosing period. Animals must be sacrificed within 24 hours of the final dose. The distribution and characterization of residues must be determined in milk, eggs, liver, kidney, muscle, and fat.

3/ If additional metabolites of concern are found in plants or animals (as required in 171-4, Nature of Residue in Plants and Animals) data may be required.

4/ The storage intervals and conditions of storage for all samples used to support established tolerances and used for additional residue data required under this standard must be submitted. These must be accompanied by data depicting the percent decline in residues under those intervals and conditions unless plant and animal commodities are stored frozen for up to 72 weeks or 4 weeks, respectively.

5/ A crop group tolerance is not appropriate at the present time because addition residue data are required for three additional members of this crop group (carrot, radish, and sugar beet); currently, potato is the only crop in this crop group on which a registered use of azinphos-methyl exists.

6/ A revised label must be submitted limiting the number of applications per growing season or establishing a minimum interval between applications.

7/ Residue data must be submitted for granules, chips, and dried potatoes processed from potatoes. It may be necessary to use exaggerated rates to obtain measurable residues in the raw agricultural commodmity. If residues concentrate in any of the processed products, appropriate food/feed additive tolerances must be processed.

TABLE A
GENERIC DATA REQUIREMENTS FOR AZINPHOS-METHYL

§158.125 Residue Chemistry - Footnotes (cont'd)

8/ A crop group tolerance is not appropriate because additional data are required to support the established tolerances for residues in or on green and dry bulb onions. Also, residue data are required for one additional group member (garlic); currently, onions is the only crop in this crop group on which registered uses of azinphos-methyl exist.

9/ The submitted data are not adequate to support the established tolerance for azinphos-methyl in or on onions (green or dry bulb). Data depicting azinphos-methyl residues in or on green onions harvested at intervals following the last three applications of 50% WP and 2 lb/gal EC formulatons, in separate tests, at 0.75 lb ai/A/application must be submitted. A minimum interval between applications must be proposed. Tests with green onions should be conducted in CA, TX, and AZ. Also data depicting azinphos-methyl residues in or on dry bulb onions harvested at intervals following the last three applications of 3%D, one of the WP, and 2 lb/gal EC formulations at 0.75 lb ai/A/ application, and 5% EC formulation at 2 tbls/gal (maximum gallons per acre must be specified). Tests with dry bulb onions should be conducted in CA, TX, NY, OR, and CO.

10/ A crop group tolerance is not appropriate at the present time because additional data are required to support the established tolerances for azinphos-methyl residues in or on celery and spinach. Residue data are also required for an additional representative crop (lettuce). Currently, celery, parsley, and spinach are the only crops in this crop group on which registered uses of azinphos-methyl exist.

11/ The available data are not adequate to support the established tolerance for residues of azinphos-methyl in or on celery. Residue data in or on untrimmed celery harvested 7 days after the last of multiple foliar applications with a WP formulation are required. The studies should take place in CA. The maximum number of applications per season, or a maximum seasonal rate should be submitted with appropriate data.

12/ The submitted data are not sufficient to support the established tolerance in or on spinach. Data depicting Azinphosthyl residues of concern in or on spinach harvested 14 days after the last of multiple foliar applications with a WP and an EC formulation (in separate tests) at 0.5 lb ai/A and, a D formulation at 0.75 lb ai/A are required. Tests must be conducted in TX, CA, NJ, OK, NY, AND AR. A maximum number of applications per season or a maximum seasonal rate must be submitted with appropriate data. The submitted data must reflect this proposed maximum.

13/ A crop group tolerance is not appropriate at the present time because additional residue data are required to support the established tolerances for residues of azinphos-methyl in or on broccoli and cabbage. Also, a use and a tolerance must be proposed and reporting residue data submitted for one additional representative commodity (mustard greens).

TABLE A
GENERIC DATA REQUIREMENTS FOR AZINPHOS-METHYL

§158.125 Residue Chemistry - Footnotes (cont'd)

14/ The available data are not sufficient to assess the established tolerance for residues of azinphos-methyl in or on broccoli. Data depicting azinphos-methyl residues of concern in or on broccoli harvested 14 days after the last of multiple foliar applications, and 21 days after the last of several transplant applications are required. Foliar applications must be made utilizing a D and an EC formulation (in separate tests) at 0.75 lb ai/A. Application must be made with ground and aerial equipment. Transplant applications must be made utilizing an EC, FlC, or WP formulation at 0.75 lb ai/A. Tests must be conducted in CA and TX. A maximum permissible number of applications per season for both transplant water and foliar applications must be proposed with the appropriate data. Tests in CA must be conducted using the same above-mentioned tests in addition to direct soil application of the 25% or 50% WP, 2 lb/gal EC, or 2 or 3 lb/gal FlC as a broadcast application at 0.75 lb ai/A.

15/ The available data are insufficient to assess the established tolerance for residues of azinphos-methyl in or on brussels sprouts. Data depicting azinphos-methyl residues of concern in or on brussels sprouts harvested 14 days after the last of multiple foliar applications, and 21 days after the last of several transplant applications are required. Foliar applications must be made utilizing a D and an EC formulation (in separate tests) at 0.75 lb ai/A. Applications must be made with ground and aerial equipment. Transplant applications must be made utilizing an EC, FlC, or WP formulation at 0.75 lb ai/A. These tests must be conducted in CA using the same above-mentioned tests in addition to direct soil application of the 25% or 50% WP, 2 lb/gal EC, or 2 or 3 lb/gal FlC as a broadcast application at 0.75 lb ai/A. A maximum number of applications per season for transplant water and foliar applications must be submitted with appropriate data.

16/ The available data are not sufficient to assess the established tolerance for residues of azinphos-methyl in or on cabbage. Data depicting azinphos-methyl residues of concern in or on cabbage harvested 14 days after the last of multiple foliar applications, and 21 days after the last of several transplant applications must be submitted. Foliar applications must be made utilizing a D and an EC formulation (in separate tests) at 0.75 lb ai/A. Application must be made with ground and aerial equipment. Transplant applications must be made utilizing an EC, FIC, or WP formulation at 0.75 lb/ai/A. These tests must be conducted in CA, FL, NY, TX, and WI. Tests in California must be conducted using the same above-mentioned tests in addition to direct soil application of the 25% or 50% WP, 2 lb/gal EC or 2 or 3 lb/gal FlC formulation as a broadcast application at 0.75 lb ai/A. The label must be revised to express the rate in terms of lbs ai/A or, if a solution, the number of gallons per acre. A maximum number of applications per season for both transplant water and foliar applications must be submitted with supporting data.

17/ The available data are not sufficient to assess the established tolerance for residues of azinphos-methyl in or on cauliflower. Data depicting azinphos-methyl residues of concern in or on caulitlower harvested 14 days after the last of multiple foliar applications, and 21 days after the last of several transplant applications, must be submitted. Foliar applications must be made utilizing a D and an EC formulation (in separate tests) at 0.75 lb ai/A. Application must be made with ground and aerial equipment and transplant applications must be made utilizing an EC, FlC, or WP at

TABLE A
GENERIC DATA REQUIREMENTS FOR AZINPHOS-METHYL

§158.125 Residue Chemistry - Footnotes (cont'd)

0.75 lb ai/A. These tests must be conducted in CA and NY. Tests in California must be conducted using the same above-mentioned tests in addition to direct soil application of the 25% or 50% WP, 2 lb/gal EC or 2 or 3 lb/gal FlC as a broadcast application at 0.75 lb ai/A. A maximum number of applications per season for transplant water and foliar applications must be submitted with appropriate supporting data. The label must be revised to express the rate in terms of lb ai/A, or, if a solution, the number of gallons per acre.

18/ A crop group tolerance is not appropriate at the present time because additional data are required to support the established tolerances for azinphos-methyl residues in or on beans (dry and snap), field peas, and soybeans.

19/ The available data are insufficient to support the established tolerances for residues of azinphos-methyl in or on dry or snap beans. Data depicting azinphos-methyl residues of concern in or on dry and snap beans following four foliar applications (in separate studies) of: (i) a WP formulation at 0.5 lb ai/A; (ii) an EC formulation at 0.5 lb ai/A; and (iii) a D formualtion at 0.6 lb ai/A are required. Aerial and ground applications must be represented. The first application should be made prior to the normal time of disease development and three additional applications should be made at regular intervals until 7 days prior to harvest (for snap beans) or 30 days prior to harvest (for dry beans). Tests with snap beans should be conducted in WI, NY, OR, and FL. Tests with dry beans should be conducted in the States of MI, CA, NE, CO, ND, and ID.

20/ The available data are insufficient to support the established tolerance for residues of azinphos-methyl in or on field peas. Data depicting azinphos-methyl residues of concern in or on field peas following four foliar applications (in separate tests) of WP and D formulations at 1 lb ai/A ar required. Aerial and ground applications must be represented. The first application should be made prior to the normal time of disease development and three additional applications should be made at regular intervals until 7 days prior to harvest. Tests should be conducted in WA and ID.

21/ The available data are insufficient to support the established tolerance for residues of azinphos-methyl in or on soybeans. Data depicting azinphos-methyl residues of concern in or on soybeans following multiple foliar applications (at regular intervals) of the D, EC, and WP formulations at 0.9 and 0.75 lb ai/A, respectively (in separate tests) are required. Aerial and ground applications must be represented. You must propose a maximum permissible number of applications per season or maximum lb ai/A/season rate. Required tests must reflect the maximum seasonal rate proposed. Tests should be conducted in IL, IA, IN, MS, MN, and OH.

22/ Data depicting residues in soybean meal, hulls, soapstock, crude oil, and refine oil from soybeans bearing measurable weathered residues are required. If residues concentrate in any of these processed commodities, appropriate food/feed additive tolerances must be proposed.

TABLE A
GENERIC DATA REQUIREMENTS FOR AZINPHOS-METHYL

§158.125 Residue Chemistry - Footnotes (cont'd)

23/ A crop group tolerance is not appropriate because additional data are required to support the existing tolerances for azinphos-methyl residues in or on pepper and tomatoes.

24/ No data were submitted for eggplants. Based on data translated from tomatoes and peppers a more appropriate tolerance level would appear to be 0.5 ppm provided a maximum of 3 applications and a 21-day PHI are imposed. If the PHI and number of applications are not acceptable, additional residue data from [illegible] and NJ reflecting the maximum proposed use will be required.

25/ The data are inadequate to assess the established tolerance for residues of azinphos-methyl in or on peppers. Data depicting azinphos-methyl residues in or on peppers harvested 14 days after the last of a minimum of four foliar applications of the 2 lb gal EC and, in a separate test, a WP formulation at 0.5 lb ai/A are required. The use of ground and aerial equipment must be represented. A maximum number of applications per season or maximum lb ai/A per season rate must be submitted and the requested data must reflect the maximum rate proposed. Tests should be conducted in FL, CA, and TX.

26/ The data are insufficient to support the established tolerance in or on tomatoes. Data depicting azinphos-methyl residues of concern in or on tomatoes following multiple foliar applications by aircraft of, in separate tests, a D formulation at 0.75 lb ai/A, a WP formulation at 1.5 lb ai/A and the 2 lb/gal EC formulation at 1.5 lb in 1 ai/A are required. The first application should be made at the normal time of disease development and be repeated at regular intervals until 14-days prior to harvest. A maximum number of applications per season or a maximum lb ai/A per season rate must be submitted. Requested data must reflect the proposed maximum rate. Tests should be conducted in FL and CA.

27/ Data depicting azinphos-methyl residues in wet and dry pomace, puree, catsup, and juice processed from tomatoes bearing measurable weathered residues are required. It may be necessary to use exaggerated rates to obtain measurable residues in the raw agricultural commodity. If residues concentrate in any of these processed products, appropriate food/feed additive tolerances must be proposed.

28/ A crop group tolerance is not appropriate because additional data are required to support the established tolerances for azinphos-methyl residues in or on cucumbers and melons and a tolerance and use directions must be submitted along with appropriate residue data for one additional group member (summer squash); currently, cucumbers and melons are the only two crops in this crop group on which registered uses of azinphos-methyl exist.

29/ The data are inadequate to assess the established tolerance for residues of azinphos-methyl in or on cucumbers. Data reflecting the residues in or on cucumbers resulting from three foliar applications of a WP and an EC formulation in separate tests at 0.5 lb ai/A are required. Cucumbers must be harvested 3 days after the final application. Tests must be conducted in MI, NC, FL, and TX.

§158.125 Residue Chemistry - Footnotes (cont'd)

30/ The available data are insufficient to support the established tolerance for residues of azinphos-methyl in or on melons. Data reflecting residues of concern in or on melons resulting from four applications (at 5- to 7-day intervals) of an EC formulation at 0.5 lb ai/A per application are required. Melons must be harvested immediately following the last foliar application. Tests with cantaloupes must be conducted in CA and TX. Tests with watermelons must be conducted in TX, FL, CA, GA, and SC. Tests with honeydew melons must be conducted in CA and TX.

31/ The submitted data are not adequate to support the established tolerance for the residues of azinphos-methyl in or on citrus fruit. The following data are required: Data depicting the residues of concern in or on oranges, grapefruit, and lemons harvested at regular intervals (until maturity) after two foliar applications of an EC and, in separate tests, of a WP formulation at 7.5 lb ai/A and 0.375 lb ai/100 gal of spray, respectively. Applications must be by aerial, and in separate tests, by ground equipment. A minimum interval between applications is required and the required studies must reflect this interval. Residue data must permit evaluation of the established PHI. Tests on oranges and grapefruit must be conducted in CA and FL and lemon tests must be conducted in CA and FL and lemon tests must be conducted in CA. A higher tolerance level proposal or a longer PHI may be acceptable.

32/ Data depicting residues of concern in citrus molasses and juice (and additional data for citrus oil) processed from fruit bearing measurable, weathered reisudes are required. Should residues concentrate in any processed commodity, appropriate food/feed additive tolerances must be proposed.

33/ A crop group tolerance is not appropriate because additional residue data are required to support the existing established tolerances for residues in or on apples and pears.

34/ The data are insufficient to support the established tolerance for residues of azinphos-methyl in or on apples. Data depicting azinphos-methyl residues of concern in or on apples harvested: (i) 15-days after the last of eight applications (including aerial and ground equipment in separate tests) at seven-day intervals of a D formulation at 2.1 lb ai/A; and (ii) seven days after the last of eight applications at seven-day intervals of a D formulation, with the first six applications made at 2.1 lb ai/A and the last two applications made at 2 lb ai/A are required.
An adjustment in use directions to establish a single PHI for all registered uses of the dust formulations may be proposed and the data requirements will then be altered to coincide with such an adjustment. Residue data are required for both EC and WP formulations: (i) 15 days after the last of eight foliar applications (at 10-day intervals) at 3.13 lb ai/A in 1,000 gal of spray suspension/A (including aerial and ground applications in separate tests); and (ii) 7-days after the last of eight ground applications; the first six made at 2.5 lb ai/A and the last two at 2 lb ai/A. Residue dta are required for a WP formulation seven days after the last of three foliar applications (at 7-day intervals) with aerial equipment at 1.5 lb ai/A. These tests should be conducted in WA, NY, and MI. Residue data are also required for an EC formulation 7 days after the last of five foliar applications (at 7-day intervals) with ULV aerial equipment at 1 lb ai/A. These tests should be conducted in ID, OR, WA, or UT since this use is limited to these States.

TABLE A
GENERIC DATA REQUIREMENTS FOR AZINPHOS-METHYL

§158.125 Residue Chemistry - Footnotes (cont'd)

35/ Depiction of residues in wet pomace, dry pomace, and juice, processed from apples bearing measurable, weathered residues is required. Appropriate food/feed additive tolerances must be proposed should concentration of residues occur in processed products.

36/ Although data are inadequate to evaluate the established tolerances, no data are required because the required apple data will be translated to crabapples, pears, and quince to evaluate their established tolerances.

37/ A crop group tolerance is not appropriate because additional data are required to support existing tolerances for residues in or on cherries, peaches, and plums and fresh prunes (refer to individual crop sections for details).

38/ The available data do not support the established tolerance for residues of azinphos-methyl in or on apricots. Data depicting the azinphos-methyl residues of concern in or on apricots harvested 21 days after the last foliar treatment of the following full-season treatment schedules: (i) three bark applications of an EC formulation and, in a separate test, a WP formulation at 0.375 lb ai/100 gal, applied at 800 gal/A; (ii) eight foliar applications of an EC formulation and, in a separate test, a WP formulation at 0.375 lb ai/100 gal, applied at 800 gal/A by ground equipment; (iii) eight foliar applications of a D formulation at 2.4 lb ai/A (aerial and ground equipment must be represented in separate tests); and (iv) multiple foliar applications of a 50 percent packeted WP at 2.5 lb ai/A applied in at least 5 gal water/A by aerial equipment are required. A label restriction giving the maximum number of applications allowed per season is also required, and the required studies must reflect that number. These studies must be conducted in CA.

39/ The available data are inadequate to support the established tolerance for residues of azinphos-methyl in or on cherries. The following data are required:

a. Data depicting azinphos-methyl residues of concern in or on cherries harvested 15 days after the last of eight foliar applications by ground and, in separate tests, by aerial equipment, of a WP and, in a separate study, an EC formulation, each at 0.5 lb ai/100 gal. You must propose a maximum gal/A/application rate and the required data must reflect the proposed maximum rate.

b. Data depicting azinphos-methyl residues of concern in or on cherries harvested 15 days after the last of eight foliar applications of a D formulation by ground and, in a separate test, aerial equipment at 2.4 lb ai/A. Tests should be conducted in WA, OR, and MI.

40/ The available data are inadequate to support the existing tolerance for residues of azinphos-methyl in or on nectarines. Data depicting the azinphos-methyl residues of concern in or on nectarines harvested 21 days after the last foliar treatment of the following full-season treatment schedules: (i) three bark applications of an EC and, in

TABLE A
GENERIC DATA REQUIREMENTS FOR AZINPHOS-METHYL

§158.125 Residue Chemistry - Footnotes (cont'd)

a separate test, a WP formulation at 0.375 lb ai/100 gal, applied at 800 gal/A; (ii) eight foliar applications of an EC and, in a separate test, of a WP formulation at 0.375 lb ai/100 gal, applied at 800 gal/A by ground equipment; (iii) eight foliar applications of a D formulation at 2.4 lb ai/A (by ground and, in a separate test, by aerial equipment) must be submitted. These studies must be conducted in CA.

41/ The available data are inadequate to support the established tolerance for residues of azinphos-methyl in or on peaches. Data depicting the azinphos-methyl residues of concern in or on peaches harvested at 21 days after the last foliar treatment of the following full-season treatment schedules: (i) three bark applications of an EC and, in a separate test, of a WP formulation at 0.375 lb ai/100 gal, applied at 800 gal/A, by ground equipment; (ii) eight foliar applications of an EC and, in a separate test, a WP formulation at 0.375 lb ai/100 gal applied at 800 gal/A by ground equipment; (iii) eight foliar applications of a D formulation at 2.4 lb ai/A (by ground and, in a separate test, by aerial equipment); and (iv) multiple foliar applications of a 50 percent packeted WP formulation at 2.5 lb ai/A in at least 5 gal water/A by aerial equipment must be submitted. A label restriction giving the maximum number of applications allowed per season are required and the required studies must reflect that number. All tests utilizing the packeted WP must be conducted in CA; all other tests must be conducted in the States of CA and GA.

42/ The available data do not provide adequate support for the established tolerance for residues of azinphos-methyl in or on plums and fresh prunes. The following data are required: Data depicting azinphos-methyl residues of concern in or on plums and fresh prunes resulting from the following full-season application schedules: (i) Three bark applications with a WP formulation and, in a separate test, with an EC formulation at 0.5 lb ai/100 gal. (ii) Eight foliar applications (at regular intervals) with a WP, and EC, and a D formulation (each in separate tests) at 0.5 lb ai/100 gal, 0.5 lb ai/100 gal, and 2.4 lb ai/A, respectively. Aerial and ground uses must be represented. A label restriction listing the maximum use rate (lb ai/A) per application for the WP and EC formulations must be proposed. The required data must reflect this proposed maximum rate. Tests must be conducted in MI, OR, and WA. (iii) Multiple foliar applications, using aerial equipment, of a WP formulation (in water-soluble packets) at 2.5 lb ai/A, applied in at least 5 gal water per acre. These studies must reflect a 21-day PHI, and must be conducted in CA. You must propose a label restriction listing the maximum number of applications allowed per season and the required data must reflect that number). Similar residue data are required for eight foliar applications of this formulation, using ground equipment, at 4 lb ai/800 gal water/A. These tests must be conducted in CA, and must reflect a 15-day PHI.

43/ Residues must be determined in dried prunes processed from plums bearing measurable weathered residues. If residues concentrate in this processed product, an appropriate food additive tolerance must be proposed.

44/ A crop group tolerance is inappropriate because additional data are required to support the established tolerances for residues of azinphos-methyl in or on the representative commodities blackberries, blueberries, cranberries, grapes and strawberries.

TABLE A
GENERIC DATA REQUIREMENTS FOR AZINPHOS-METHYL

§158.125 Residue Chemistry - Footnotes (cont'd)

45/ The available data are insufficient to support the established tolerance for residues of azinphos-methyl in or on blackberries. Data depicting azinphos-methyl residues of concern in or on blackberries 14 days after the last of two foliar applications of: (i) an EC formulation applied aerially at 0.51 lb/A; (ii) a WP formulation applied aerially at 0.51 lb ai/A; (iii) a D applied with ground equipment at 0.9 lb ai/A; and (iv) a D applied aerially at 0.9 lb ai/A are required. Data are also required depicting residues of concern in or on blackberries 3 days after the last of two soil applications of, in separate tests, EC and WP formulations at 2 lb ai/A. A minimum interval between applications must be proposed and tests should be conducted in OR and CA.

46/ The available data are not adequate to support the established tolerance. The following data are required:

a. Depiction of azinphos-methyl residues of concern in or on blueberries following aerial applications of a D formulation as follows: (i) from samples harvested four hours after the last of two applications at 0.6 lb ai/A; (ii) from samples harvested 9 hours after the last of five applications at 0.6 lb ai/A; and (iii) from samples harvested 14 days after the last two applications at 0.9 lb ai/A.

b. Depiction of the same residues following ground applications of a D formulation as follows: (i) from samples harvested 7 days after the last of two application at 0.6 lb ai/A; and (ii) from samples harvested 14 days after the last of two applications at 0.9 lb ai/A. For all tests, applications made more than 14 days prior to harvest must be at 0.9 lb ai/A.

c. Depiction of the same residues following ground and aerial applications of an EC and a WP formulation (all in separate tests) as follows: (i) from samples harvested 3 days after the last of four applications at 0.75 lb ai/A; and (ii) 14 days after the last of two applications made at 1.0 lb ai/A. For all tests, applications made more than 14 days prior to harvest must be at 1 lb ai/A. Tests should be conducted in MI and NJ. A minimum interval between applications must be submitted.

47/ The available data are insufficient to support the established tolerance for residues of azinphos-methyl in or on boysenberries. No additional data, however, are required because data for blackberries will be translated to boysenberries.

48/ The available data are insufficient to support the established tolerance for residues of azinphos-methyl in or on cranberries. Data depicting azinphos-methyl residues of concern in or on cranberries following multiple foliar applications of, in separate tests, a D formulation at 0.92 lb ai/A, a WP formulation at 1 lb ai/A, and an EC formulaton at 1 lb ai/A are required. Applications must commence prior to the normal time of disease development and be repeated at 7-day intervals until 21 days prior to harvest. Aerial and ground application must be represented. A maximum number of applications per season or maximum lb ai/A per season must be proposed and the required data should reflect the proposed maximum rate. Tests should be conducted in WI and MA.

TABLE A
GENERIC DATA REQUIREMENTS FOR AZINPHOS-METHYL

§158.125 Residue Chemistry - Footnotes (cont'd)

49/ There are not registered uses for azinphos-methyl on gooseberries. You must propose use directions and provide supporting residue data that reflect the maximum proposed rate or you may elect to cancel the tolerance.

50/ The available data indicate that the registered uses will likely result in residues exceeding the presently established tolerance for grapes. The available data are insufficient to propose a new tolerance level for residues of azinphos-methyl in or on grapes. Data depicting azinphos-methyl residues of concern in or on grapes following three foliar applications of a D formulation as follows: (i) immediately after the last application at 0.7 lb ai/A; and (ii) 10 days after the last application at 0.9 lb ai/A are required. Applications made more than 10 days before harvest applications must be made at the maximum permitted rate of 0.9 lb ai/A. Data are also required depicting similar residues from application of EC and WP formulations in separate tests, as follows:
(i) immediately after the last application at 0.75 lb ai/A;
(ii) 10 days after the last application at 1.13 lb ai/A; and
(iii) 28 days after the last application at 1.5 lb ai/A.
Applications made more than 28 days before harvest must be made at the maximum permitted rate of 1.5 lb ai/A. Aerial and ground use must be represented. Tests should be conducted in CA and NY.

51/ Data depicting residues in wet and dry pomace, raisins and raisin waste processed from grapes bearing measurable, weathered residues are required. If residues concentrate in any of these processed commodities, appropriate food/feed additive tolerances must be proposed.

52/ The available data are insufficient to support the established tolerances for residues of azinphos-methyl in or on loganberries and raspberries. No additional data are required, however, because required data for blackberries will be translated to loganberries and raspberries.

53/ The available data are insufficient to support the established tolerance for residues of azinphos-methyl in or on strawberries. Data depicting azinphos-methyl residues of concern in or on strawberries following multiple foliar applications (at regular intervals) of a D formulation and in separate tests, a WP and EC formulation at 0.5 lb ai/A are required. The first application should be made at the normal time of disease development and applications must be repeated at regular intervals until 5 days prior to harvest. Aerial and ground use must be represented. You must propose a maximum number of applications per season or maximum seasonal rate per acre and the required data must reflect the proposed maximum rate. Tests should be conducted in CA and FL.

54/ A crop group tolerance is not appropriate because additional data are required to support the established tolerances for residues in or on almonds, pecans, and walnuts.

§158.125 Residue Chemistry - Footnotes (cont'd)

55/ The available data do not support the established tolerance for azinphos-methyl residues in or on almonds and almond hulls. Data depicting azinphos-methyl residues of concern in and on almonds (nutmeats and hulls) harvested after two foliar applications of the EC formulation at 2.5 lb ai/A (applied in 500 gal/A) using ground and aerial equipment are required. Applications must be 30 days apart. These studies must reflect a 60-day PHI, and must be conducted in CA.

56/ The available data do not support the established tolerance for residues of azinphos-methyl in or on filberts. Data from studies depicting azinphos-methyl residues of concern in and on filberts harvested after multiple foliar applications of an EC and, in separate tests, a WP formulation at 7.5 lb ai/A (0.75 lb ai/100 gal water, applied at 1,000 gal/A) are required. Tests must reflect the use of ground and aerial equipment, must reflect a 30-day PHI, and must b conducted in OR and WA. You must propose a label restriction that gives the maximum number of applications allowed per season and the data required above must reflect that number.

57/ The available data do not support the established tolerance for residues of azinphos-methyl in or on pecans. Data depicting azinphos-methyl residues in and on pecans harvested on the day of the last of a series of multiple foliar applications (ending prior to husk split) of a WP formulation and, in separate tests, of an EC formulation, applied at 10.08 lb ai/A (0.56 lb ai/100 gal, at 1800 gal/A) are required. Separate tests should reflect ground and aerial application of each formulation. In lieu of conducting tests reflecting a 0-day posttreatment interval, an alternate PHI may be proposed and submitted with residue data. The studies must be conducted in GA, NM, LA, AL, and TX. You must propose a label restriction that gives the maximum number of applications allowed per season and the data required above must reflect that number.

58/ The available data do not support the established tolerance for residues of azinphos-methyl in or on walnuts. Data depicting residues of azinphos-methyl residues of concern in and on walnuts harvested on the day of the last of a series of foliar applications (ending prior to husk split) of a WP formulation, and in separate tests, an EC formulation, applied at 10.34 lb ai/A by ground and, in separate tests, by aerial equipment are required. Separate studies must reflect application of a D formulation by ground and, in separate tests, by air, at 1.5 lb ai/A. These studies must be conducted in CA. A label restriction that gives the maximum number of applications allowed per season must be submitted and the data required above must reflect that number.

59/ A crop group tolerance is inappropriate because additional residue data are required to support the existing tolerance for azinphos-methyl residues in or on wheat and tolerances must be established and appropriate supporting data provided for additional representative commodities (corn [fresh sweet and dried filed], rice, and sorghum).

60/ The data are insufficient to assess the established tolerances for residues of azinphos-methyl in or on oat, rye, and barley grain. No additional data are required because the required data for wheat will be translated to oat, rye, and barley grain.

TABLE A
GENERIC DATA REQUIREMENTS FOR AZINPHOS-METHYL

§158.125 Residue Chemistry - Footnotes (cont'd)

61/ The data are insufficient to assess the established tolerance for residues of azinphos-methyl in or on wheat grain. Data depicting azinphos-methyl residues of concern in or on wheat grain harvested 30 days following a single foliar application of an EC formulation and, in a separate test, a WP or a FlC formulation at 0.5 lb ai/A with a 30-day pre-harvest interval are required. Tests must reflect both ground and aerial applications. Tests should be conducted in KS, ND, WA, TX, OK, and MT.

62/ Data depicting azinphos-methyl residues in milled products processed from wheat bearing measurable weathered residues are required. If residues concentrate in milled products, an appropriate food/feed additive tolerance must be proposed.

63/ A crop group tolerance is inappropriate at the present time because additional residue data are required to support the established tolerances for wheat straw and one other cereal forage crop (barley forage, hay and straw; oat forage, hay and straw; rye straw; or sorghum forage, fodder, hay and silage). A tolerance poposal must be submitted for corn forage, fodder, and silage.

64/ The data are insufficient to assess the established tolerances for residues of azinphos-methyl in or on barley, oat, or rye straw however, no additional data are required, since the required data for wheat straw will be translated to barley, oat, and rye straw.

65/ The data are insufficient to assess the established tolerance for residues of azinphos-methyl in or on wheat straw. Data depicting azinphos-methyl residues of concern in or on wheat straw harvested 30 days following a single foliar application of an EC formulation and, in a separate test, a WP formulation at 0.5 lb ai/A are required. Applications must be made using both ground and aerial equipment. Tests should be conducted in KS, ND, WA, TX, OK, and MT.

66/ A crop group tolerance is inappropriate at the present time because use directions and tolerances must be submitted and appropriate supporting residue data provided for bermuda grass, bluegrass, and bromegrass for fescue.

67/ The available data are not adequate to support the established tolerance for residues of azinphos-methyl in or on grass forage and hay. Data depicting azinphos-methyl residues of concern in or on pasture grass and pasture grass hay harvested 0 days following a single foliar application of appropriate formulations of azinphos-methyl at the maximum established use rate are required. Separate tests must be conducted using aerial and ground equipment. Tests should be conducted in WI, NY, PA, MN, IA and MI.

§158.125 Residue Chemistry - Footnotes (cont'd)

68/ A crop group tolerance is not appropriate at present because additional data are required for alfalfa and clover, the representative commodities of this group.

69/ The available residue data indicate the established tolerances for alfalfa hay and forage are too low. New tolerance levels cannot be proposed at this time because no data were submitted depicting residues resulting from the registered uses with a dust formulation. Data depicting azinphos-methyl residues of concern in or on alfalfa forage and hay: (i) 21 days following a single application at 0.75 lb ai/A; (ii) 16 days following a single application at 0.5 lb ai/A; (iii) 14 days after the second of two applications at 0.25 lb ai/A; (iv) and 14 days after single application at 0.375 lb ai/A are required. Separate tests must be conducted with D and WP or FlC formulations, and with aerial and ground equipment. Tests should be conducted in CA, ID, IA, NE, NV, SD, UT, and WI. Tests from CA, UT, and NV must include irrigated regions.

70/ No data were submitted to support the established tolerances for residues of azinphos-methyl in or on birdsfoot trefoil forage and hay. However, no data are required since the requested data for clover will be translated to birdsfoot trefoil.

71/ The available data are insufficient to support the established tolerances for residues of azinphos-methyl in or on clover forage and hay. Data depicting azinphos-methyl residues of concern in or on clover forage and hay: (i) 21 days after a single application at 0.75 lb ai/A; (ii) 16 days after a single application at 0.5 lb ai/A; (iii) 14 days after the last of two applications at 0.25 lb ai/A; and (iv) 14 days after a single application at 0.375 lb ai/A are required. For determination of residues in or on clvoer hay, separate tests must be conducted with D and WP or FlC formulations and with aerial and ground applications. For determination of residues in clover forage, the same data are required, except that tests depicting residues from ground applications of EC or WP formulations are not required. Tests should be conducted in CA, KY, MO, NY, OK, PA, TN, and TX. Tests from CA must include irrigated regions.

72/ The submitted data are insufficient to support the established tolerance for residues of azinphos-methyl in or on artichokes. Data depicting azinphos-methyl residues of concern in or on artichokes harvested 30 days following multiple foliar applications of, in separate tests, a WP formulation and the 2 lb/gal EC formulation at 1.5 lb ai/A are required. A maximum permissible number of applications per season or a maximum lb ai/A/season rate must be proposed and required tests must reflect the maximum seasonal rate proposed. Tests should be conducted in CA.

73/ No tolerance has been established or proposed pertaining to residues of azinphos-methyl in or on cotton forage. Since cotton forage is a raw agricultural commodity, the registrant must either propose a tolerance for cotton forage and provide the appropriate supporting residue data, or propose feeding and grazing restrictions. In addition, the

TABLE A
GENERIC DATA REQUIREMENTS FOR AZINPHOS-METHYL

§158.125 Residue Chemistry - Footnotes (cont'd)

submitted data are insufficient to support the established tolerance for residues of azinphos-methyl in or on cottonseed the following data are required:

a. Data depicting azinphos-methyl residues of concern in or on cottonseed following multiple foliar applications of the 3 percent D formulation at 1 lb ai/A. Foliar applications should begin prior to the normal time of disease development and continue at regular intervals until 1 day prior to harvest. A maximum number of applications per season or maximum lb ai/A/season must be proposed and required data must reflect the proposed rate. Ground and aerial equipment must be presented.

b. Data depicting azinphos-methyl residues of concern in or on cottonseed following multiple ULV applications of a registered FlC formulation at 0.25 lb ai/A. Foliar applications should begin at the normal time of bollweevil infestation and be repeated at regular intervals until 1 day prior to harvest. A maximum number of applications per season or maximum pounds ai/A/season must be proposed. Tests should be conducted in TX, CA, and MS.

74/ Data depicting residues in meal, hulls, and crude oil, refined oil and soapstock processed from cottonseed bearing measureable weathered residues are required. If residues concentrate in any of these processed commodities, appropriate food/feed additive tolerances must be proposed.

75/ A maximum number of applications per season or maximal seasonal rate must be submitted with the appropriate data. If the proposed use rate exceeds that reflected in the submitted data, then data depicting azinphos-methyl residues in or on kiwi fruit following multiple foliar applications (at regular intervals) of the 50% WP formulation at 50 g ai/100 L (using 2,200 L/Ha) until 14 days prior to harvest must be submitted.

76/ The available data are adequate to support the established tolerances for sugarcane and sugarcane bagasse and the submitted data for residues in sugar and molasses are sufficient to show that azinphos-methyl residues do not concentrate in these processed products. No tolerance, however, has been established or proposed for residues of azinphos-methyl in or on sugarcane forage. Since sugarcane forage is a raw agricultural commodity, you must either submit labeling imposing feeding restrictions or propose a tolerance and provide data depicting azinphos-methyl residues of concern in or on sugarcane forage following five broadcast applications by aircraft of a G formulation at 1 lb ai/A and, in separate tests, five foliar applications of EC and FlC formulations at 0.75 lb ai/A. The last application conducted in FL and LA.

77/ No data are available to assess the exposure of man to residues of concern of azinphos-methyl in or on tobacco and its products. The following data are required:

a. Depictions of residues of concern in or on tobacco harvested at regular intervals until maturity, beginning six days after the last of multiple foliar applications of a D, EC, or WP formulaton at 7-day intervals at 0.75 lb

TABLE A
GENERIC DATA REQUIREMENTS FOR AZINPHOS-METHYL

§158.125 Residue Chemistry - Footnotes (cont'd)

ai/A. Applications must commence immediately after transplanting or when pests first appear. Residue data are required for both green and cured tobacco, and for tobacco smoke.

b. If total residues found in or on tobacco from the above requested studies are > 0.1 ppm, then complete analytical methods must be submitted for detecting and quantifying azinphos-methyl and all metabolites of concern in or on tobacco and in tobacco smoke.

c. If total residues found in or on green tobacco are > 0.1 ppm then pyrolysis products from azinphos-methyl must be characterized using ^{14}C-ring labeled azinphos-methyl.

o All significant tobacco plant metabolites must be determined using ^{14}C-ring labeled azinphos-methyl.

78/ The nature of the residue in ruminants is not adequately understood. The adequacy of the established tolerances cannot be assessed, until the required residue data for the agricultural commodities and processed products o animal feeds are submitted and reviewed.

TABLE A
GENERIC DATA REQUIREMENTS FOR AZINPHOS-METHYL

Data Requirement	Test Substance	Use Patterns	Does EPA Have Data?	Bibliographic Citation	Must Additional Data be Submitted?	Time Frame for Submission
§158.130 Environmental Fate						
DEGRADATION STUDIES-LAB:						
161-1 - Hydrolysis	TGAI or PAIRA	A,B,G	Yes	00029899	No	
Photodegradation						
161-2 - In water	TGAI or PAIRA	A,B,G,	No		Yes	9 Months
161-3 - On soil	TGAI or PAIRA	A,G	No		Yes	9 Months
161-4 - In Air	TGAI or PAIRA	A	No		Reserved 1/	
METABOLISM STUDIES-LAB:						
162-1 - Aerobic Soil	TGAI or PAIRA	A,B,G	Yes	00029900	No	
162-2 - Anaerobic Soil	TGAI or PAIRA	A	Yes	00029900	No	
162-3 - Anaerobic Aquatic	TGAI or PAIRA	G	No		Yes 5/	27 Months
MOBILITY STUDIES:						
163-1 - Leaching and Adsorption/Desorption	TGAI or PAIRA	A,B,G	Yes	00029885 00029887	No	
163-2 - Volatility (Lab)	TEP	A	No		Reserved 1/	
163-3 - Volatility (Field)	TEP	A	No		Reserved 1/	

TABLE A
GENERIC DATA REQUIREMENTS FOR AZINPHOS-METHYL

Data Requirement	Test Substance	Use Patterns	Does EPA Have Data?	Bibliographic Citation	Must Additional Data be Submitted?	Time Frame for Submission
§158.130 Environmental Fate - Continued						
DISSIPATION STUDIES-FIELD:						
164-1 - Soil	TEP	A,B	Yes	00144667 00144669 00144673	No	
164-3 - Forestry	TEP	G	No		Yes/5	27 Months
164-5 - Soil, Long-term	TEP	A,B	No		No 2/	
ACCUMULATION STUDIES:						
165-1 - Rotational Crops (Confined)	PAIRA	A	No		Yes	39 Months
165-2 - Rotational Crops (Field)	TEP	A	No		Reserve 3/	
165-3 - Irrigated Crops	TEP	A	No		Yes 4/	39 Months
165-4 - In Fish	TGAI or PAIRA	A,B,G	Yes	00112146	No	
165-5 - In Aquatic Non-Target Organisms	TEP	G	No		Yes 5/	12 Months

TABLE A
GENERIC DATA REQUIREMENTS FOR AZINPHOS-METHYL

§158.130 Environmental Fate - Continued

1/ Data reserved pending the outcome of reentry exposure and dissipation data requirements (132-1 - 133-4)
2/ Because of the low persistence of azinphos-methyl these data are not required.
3/ Reserved pending the result of the confined rotational crop study (165-1).
4/ Data will not be needed if the label contains a statment prohibiting use of water leaving treated field for purposes of irrigating other crops.
5/ These data may be waived if forest use is removed from the label, or if the use is defined as referring to tree plantations that are not truly forest environments.

TABLE A
GENERIC DATA REQUIREMENTS FOR AZINPHOS-METHYL

Date Requirement	Test Substance	Use Patterns	Does EPA Have Data?	Bibliographic Citation	Must Additional Data be Submitted	Time Frame for Submission
§158.135 Toxicology						
ACUTE TESTING:						
81-1 - Acute Oral Toxicity - Rat	TGAI	A,B	Yes	00155000 00155001 00155002 00155003	No	
81-2 - Acute Dermal Toxicity - Rabbit	TGAI	A,B	Yes	00155002 00155003	No	
81-3 - Acute Inhalation Toxicity - Rat	TGAI	A,B	No	-	Yes	9 Months
81-7 - Delayed Neurotoxicity - Hen	TGAI	A,B	No	-	Yes	12 Months
SUBCHRONIC TESTING:						
82-1 - 90-Day Feeding:	TGAI					
- Rodent, and		A,B	No	-	No 1/	
- Non-rodent (Dog)		A,B	Yes	0083620	No 2/	
82-4 - 90-Day Inhalation: - Rat	TGAI	A,B	Yes	00155011	No	

TABLE A
GENERIC DATA REQUIREMENTS FOR AZINPHOS-METHYL

Data Requirement	Test Substance	Use Patterns	Does EPA Have Data?	Bibliographic Citation	Must Additional Data be Submitted?	Time Frame for Submission
§158.135 Toxicology - Continued						
CHRONIC TESTING:						
83-1 - Chronic Toxicity - 2 species:	TGAI					
- Rodent, and		A,B	No	-	Yes	50 Months
- Non-rodent (Dog)		A,B	Yes	00083620	No	
83-2 - Oncogenicity - 2 species:	TGAI					
- Rat (preferred), and		A,B	Yes	GS0235055	Yes 3/	50 Months
- Mouse (preferred)		A,B	Yes	GS0235055	No	
83-3 - Teratogenicity - 2 species:	TGAI					
- Rat		A,B	No	-	Yes	15 Months
- Rabbit		A,B	No	-	Yes	15 Months
83-4 - Reproduction - Rat 2-generation	TGAI	A,B	No	-	Yes	39 Months
MUTAGENICITY TESTING						
84-2 - Gene Mutation (Ames Test)	TGAI	A,B	No	-	Yes	9 Months
84-2 - Structural Chromosomal Aberration	TGAI	A,B	No	-	Yes	12 Months
84-4 - Other Genotoxic Effects	TGAI	A,B	Yes	00155017	No	

TABLE A
GENERIC DATA REQUIREMENTS FOR AZINPHOS-METHYL

Data Requirement	Test Substance	Use Pattern	Does EPA Have Data?	Bibliographic Citation	Must Additional Data be Submitted?	Time Frame for Submission
§158.135 Toxicology - Continued						
SPECIAL TESTING						
85-1 - General Metabolism	PAI or PAIRA	A,B	No	-	Yes	24 Months

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1/ The required chronic toxicity will satisfy this requirement.
2/ The chronic toxicity study in dogs satisfies this requirement.
3/ The available rat data are inadequate and a rat oncogenicity study must be submitted.

TABLE A
GENERIC DATA REQUIREMENTS FOR AZINPHOS-METHYL

Data Requirement	Test Substance	Use Pattern	Does EPA Have Data?	Bibliographic Citation	Must Additional Data be Submitted?	Time Frame for Submission
§158.140 Reentry Protection						
132-1 - Foliar Dissipation	TEP	A	No		Yes	16 Months
132-2 - Soil Dissipation	TEP	A	No		Yes	27 Months
133-3 - Dermal Exposure	TEP	A	No		Yes	16 Months
133-4 - Inhalation Exposure	TEP	A	No		Yes	16 Months
158.75 Other Exposure Data						
- Glove Permeability Study	1/	A	No		Yes	9 Months

1/ A glove permeability study must be submitted using liquid and wettable powder formulations. The study must use several different materials and must be conducted according to methods outlined in the "Standard Test Method for Resistance of Protective Clothing Materials to Permeation by Hazardous Liquid Chemicals" by the American Society for Testing and Materials. A protocol must be submitted to the Agency within 3 months of the issuance of the guidance document. The permeability studies for the wettable powder formulations shall be conducted using the highest label permitted spray solution concentration.

TABLE A
GENERIC DATA REQUIREMENTS FOR AZINPHOS-METHYL

Data Requirement	Test Substance	Use Pattern	Does EPA Have Data?	Bibliographic Citation	Must Additional Data be Submitted?	Time Frame for Submission
§158.145 Wildlife and Aquatic Organisms						
AVIAN AND MAMMALIAN TESTING						
71-1 - Acute Avian Oral Toxicity	TGAI	A,B,G	No	-	Yes 1/	9 Months
71-2 - Avian Subacute Dietary Toxicity	TGAI					
- Upland Game Bird, and		A,B,G	Yes	00034769	No	
- Waterfowl		A,B,G	Yes	00034769	No	
71-3 - Wild Mammal Toxicity	TGAI	A,B,G	No	-	Yes 2/	24 Months
71-4 - Avian Reproduction	TGAI					
- Upland Game Bird, and		A,B,G	No	-	Yes 3/	24 Months
- Waterfowl		A,B,G	No	-	Yes 3/	24 Months
71-5 - Actual Field Testing	TEP					
- Mammals, and		A,B,G	No	-	Yes 4/	48 Months
- Birds		A,B,G	No	-	Yes 4/	48 Months

TABLE A
GENERIC DATA REQUIREMENTS FOR AZINPHOS-METHYL

Data Requirement	Test Substance	Use Pattern	Does EPA Have Data?	Bibliographic Citation	Must Additional Data be Submitted?	Time Frame for Submission
§158.145 Wildlife and Aquatic Organisms - Continued						
AQUATIC ORGANISM TESTING						
72-1 - Freshwater Fish Toxicity	TGAI					
- Coldwater Fish Species, and		A,B,G	Yes	GS0144012	No	
- Warmwater Fish Species		A,B,G	Yes	GS0144012	No	
- Freshwater Fish Toxicity	TEP					
- Coldwater Fish Species, and		A,B,G	Yes	00066046 GS0235005	No	
- Warmwater Fish Species		A,B,G	Yes	00066046	No	
72-2 - Acute Toxicity to Freshwater Invertebrates	TGAI	A,B,G	Yes	GS0144012 00068678	No	
- Acute Toxicity to Freshwater Invertebrates	TEP	A,B,G	No	-	Yes 5/	9 Months
72-3 - Acute Toxicity to Estuarine and Marine Organisms	TGAI					
- Fish		A	No	-	Yes 6/	12 Months
- Mollusk		A	No	-	Yes 6/	12 Months
- Shrimp		A	No	-	Yes 6/	12 Months

TABLE A
GENERIC DATA REQUIREMENTS FOR AZINPHOS-METHYL

Data Requirement	Test Substance	Use Pattern	Does EPA Have Data?	Bibliographic Citation	Must Additional Data be Submitted?	Time Frame for Submission
§158.145 Wildlife and Aquatic Organisms - Continued						
72-4 - Fish Early Life Stage, and	TGAI	A,B,G	Yes	00145592	Yes 7/	15 Months
-Aquatic Invertebrate Life-Cycle	TGAI	A,B,G	Yes	00143785	No	
72-5 - Fish Life -Cycle	TGAI	A,B,G	No	-	Reserved 8/	
72-6 - Aquatic Organism Accumulation	TGAI, PAI OR Degradation Product	A,B,G	Yes	00112146	No	
72-7- Simulated or Actual Field Testing for Aquatic Organism	TEP	A,B,G	No	-	Yes 9/	24 Months (Simulated Study) OR 48 Months (Actual Study)

TABLE A
GENERIC DATA REQUIREMENTS FOR AZINPHOS-METHYL

§158.145 Wildlife and Aquatic Organisms - Continued

1/ A study meeting current guideline requirements is needed. Granule weight data for granular formulations is also required.

2/ A five-day dietary study is required as per 40 CFR 158.145, to provide information on a species actually exposed in the field, with a dietary feeding type of ingestion.

3/ Avian reproduction studies with technical azinphos-methyl are required by 40 CFR 158.145, since birds may be subjected to repeated exposure preceding and/or during the breeding season. Current labeling permits applications for most use sites and rates, often without specific restriction as to the number of such applications.

4/ Actual field testing with birds and mammals is required, as per 40 CFR 158. 145. With a typical non-granular formulation, the initial sites to be tested (based on application rates and wildlife usage information) include apple, cherry, and walnut orchards. Initial testing must include a study of dietary exposure and thorough carcass searching to determine whether there is pesticide induced mortality, and if so, the extent. Research for the apple site must also determine, by nest survey, whether avian breeding is disrupted, and collect complete natality, mortality, emigration, and immigration data. It must be determined, by mark-recapture techniques, whether mammalian populations are affected. Also required is a field study of broadcast application of the 10% granular formulation in sugarcane at 1 lb a.i./A, with carcass searching as described above. Multiple sites are required for all use patterns studied. Additional field testing is reserved pending results of these studies. Cancellation of any of the above use patterns would obviate the need for testing of these uses. However, depending on the outcome of the above listed studies, other sites may be required. Protocols for conducting the studies must be submitted to the Agency for review and approval within 6 months of the receipt of the guidance document.

5/ An acute toxicity study using an end use product with a freshwater invertebrate species is needed for hazard evaluation since 1) the LC_{50} of the technical grade of active ingredient is less than or equal to the estimated environmental concentration (EEC) in the aquatic environment in modeled use patterns and 2) for forest use, there is a potential for direct application to water under the forest canopy (see 40 CFR 158.145).

TABLE A
GENERIC DATA REQUIREMENTS FOR AZINPHOS-METHYL

§158.145 Wildlife and Aquatic Organisms - Continued

6/ Acute toxicity studies with estuarine and marine organisms are needed because available runoff modeling information and certain coastal area uses indicates a likelihood for exposure.

7/ The existing study did not find an overall no-effect level and raw data were not submitted for analysis. A new study is required.

8/ This study is reserved pending submission and review of the required fish embryolarvae study.

9/ The Agency presumes substantial acute hazard from azinphos-methyl (see 40 CFR 154.7). Estimates of aquatic exposure and measured field residues are greater than many acute LC_{50} values, and aquatic field kills have been found. A field monitoring study was required in a 5-3-82 EEB review, but this was in regard to a proposed corn use not covered by this Standard. A simulated field study (mesocosm) was required in a 10-16-85 review, and should be applicable to the use patterns covered by this Registration Standard, if conducted at appropriate loading rates. In addition, aquatic field studies must be conducted on those registered sites for which greatest hazard may be anticipated. These include sugarcane, potatoes, and blueberries, since the PIMS reports implicate these sites. Cotton and soybeans should be included because of available modeling with these crops. A high application rate orchard site such as walnuts should also be included. Pine forest is a substantially different use pattern that should also be included in order to cover forestry uses. Aquatic residue monitoring (water column and sediments) is required for all of these sites under "worst-case" situations (e.g., following rainfall). A full-scale aquatic field study (examining effects on aquatic invertebrates and fish in addition to residue monitoring) is an alternative to a mesocosm study and, if chosen, must be conducted on a cotton site since this is the largest use-site for this pesticide. However, a mesocosm study, using both fish and aquatic invertebrates, is likely to be more applicable to other registered sites. Additional residue monitoring and full-scale field studies are reserved pending results of these studies. Cancellation of any of the above use patterns would obviate the need for testing of these uses. However, since further studies are pending the results of the above initial testing, other sites may be required to be substituted. Protocols for conducting the studies must be submitted to the Agency for review and approval within 6 months of the receipt of this document.

TABLE A
GENERIC DATA REQUIREMENTS FOR AZINPHOS-METHYL

Data Requirement	Test Substance	Use Pattern	Does EPA Have Data?	Bibliographic Citation	Must Additional Data be Submitted?	Time Frame for Submission
§158.155 Nontarget Insect						
NONTARGET INSECT TESTING - POLLINATORS:						
141-1 - Honey bee acute contact toxicity	TGAI	A,B,G,H	Yes	00066220 05004151	No	
141-2 - Honey bee - toxicity of residues on foliage	TEP	A,B,G,H	No		Yes 1/	15 Months
141-4 - Honey bee subacute feeding study					(Reserved) 2/	
141-5 - Field testing for pollinators	TEP	A,B,G,H	No		No 3/	
NONTARGET INSECT TESTING - AQUATIC INSECTS:						
142-1 - Acute toxicity to aquatic insects					(Reserved) 4/	
142-1 - Aquatic insect life-cycle study					(Reserved) 4/	
142-3 - Simulated or actual field testing for aquatic insects					(Reserved) 4/	

TABLE A
GENERIC DATA REQUIREMENTS FOR AZINPHOS-METHYL

Data Requirement	Test Substance	Use Pattern	Does EPA Have Data?	Bibliographic Citation	Must Additional Data be Submitted?	Time Frame for Submission
143-1 - NONTARGET INSECT thru TESTING - PREDATORS 143-3 AND PARASITES					(Reserved) 4/	

1/ As data from the acute study indicate high toxicity to honeybees, data on residual toxicity are required.

2/ Reserved pending development of test methodology.

3/ Requirement for field testing is imposed only on a case-by-case basis. Data reviewed to date do not indicate the need for a field study.

4/ Reserved pending the Agency decision as to whether the data requirement should be established.

TABLE B
PRODUCT SPECIFIC DATA REQUIREMENTS FOR MANUFACTURING-USE PRODUCTS CONTAINING AZINPHOS-METHYL

Data Requirement	Test Substance	Use Pattern	Does EPA Have Data? 1/	Bibliographic Citation	Must Additional Data be Submitted?	Time Frame for Submission
§158.120 Product Chemistry						
Product Identity:						
61-1 - Product Identity and Disclosure of Ingredients	MP	All	No	-	Yes 2/	6 Months
61-2 - Description of Beginning Materials and Manufacturing Process	MP	All	No	-	Yes 2/	6 Months
61-3 - Discussion of Formation of Impurities	MP	All	No	-	Yes 2/	6 Months
Analysis and Certification of Product Ingredients						
62-1 - Preliminary Analysis	MP	All	No	-	Yes 2/	12 Months
62-2 - Certification of Limits	MP	All	No	-	Yes 2/	12 Months
62-3 - Analytical Methods to Verify Certified Limit	MP	All	No	-	Yes 2/	12 Months
Physical and Chemical Characteristics						
63-2 - Color	MP	All	No	-	Yes 2/	6 Months
63-3 - Physical State	MP	All	No	-	Yes 2/	6 Months
63-4 - Odor	MP	All	No	-	Yes 2/	6 Months

TABLE B
PRODUCT SPECIFIC DATA REQUIREMENTS FOR MANUFACTURING-USE PRODUCTS CONTAINING AZINPHOS-METHYL

Data Requirement	Test Substance	Use Pattern	Does EPA Have Data? 1/	Bibliographic Citation	Must Additional Data be Submitted? 2/	Time Frame for Submission
§158.120 Product Chemistry (Continued)						
Physical and Chemical Characteristics (Continued)						
63-7 - Density, Bulk Density, or Specific Gravity	MP	All	No	-	Yes 2/	7 Months
63-12 - pH	MP	All	No	-	Yes 2/	7 Months
63-14 - Oxidizing or Reducing Action	MP	All	No	-	Yes 2/	7 Months
63-15 - Flammability	MP	All	No	-	Yes 2/	7 Months
63-16 - Explodability	MP	All	No	-	Yes 2/	7 Months
63-17 - Storage Stability	MP	All	No	-	Yes 2/	16 Months
63-18 - Viscosity	MP	All	No	-	Yes 2/	7 Months
63-19 - Miscibility	MP	All	No	-	Yes 2/	7 Months
63-20 - Corrosion Characteristics	MP	All	No	-	Yes 2/	7 Months

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1/ Although product chemistry data may have been submitted in the past, the Agency has determined that these data must be resubmitted for each manufacturing use product. New requirements have been introduced and previously submitted data must be updated. Therefore bibliographic citations for the old data are not applicable.

2/ Product Specific data are required for the following formulations: EPA REG. NO. 3125-108, EPA REG. NO. 11678-4, EPA REG. NO. 2749-291, EPA REG. NO. 10163-95, EPA REG. NO. 3125-225, EPA REG. NO. 3125-153, EPA REG. NO. 3125-223.

TABLE B
PRODUCT SPECIFIC DATA REQUIREMENTS FOR MANUFACTURING-USE PRODUCTS CONTAINING AZINPHOS-METHYL

Data Requirement	Test Substance	Use Pattern	Does EPA Have Data?	Bibliographic Citation	Must Additional Data be Submitted? 1/	Time Frame for Submission
§158.135 Toxicology						
ACUTE TESTING						
81-1 - Acute Oral Toxicity - Rat	MP	All	No	-	Yes 1/	9 Months
81-2 - Acute Dermal Toxicity - Rabbit	MP	All	No	-	Yes 1/	9 Months
81-3 - Acute Inhalation Toxicity - Rat	MP	All	No	-	Yes 1/	9 Months
81-4 - Primary Eye Irritation - Rabbit	MP	All	No	-	Yes 1/	9 Months
81-5 - Primary Dermal Irritation - Rabbit	MP	All	No	-	Yes 1/	9 Months
81-6 - Dermal Sensitization - Guinea Pig	MP	All	No	-	Yes 1/	9 Months

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1/ Product Specific data are required for the following formulations: EPA REG. NO. 3125-108, EPA REG. NO. 11678-4, EPA REG. NO. 2749-291, EPA REG. NO. 10163-95, EPA REG. NO. 3125-225, EPA REG. NO. 3125-153, EPA REG. NO. 3125-223.

TABLE C
PRODUCT SPECIFIC DATA REQUIREMENTS FOR END-USE PRODUCTS CONTAINING AZINPHOS-METHYL

Data Requirement	Test Substance	Use Pattern	Does EPA Have Data?	Bibliographic Citation	Must Additional Data be Submitted?	Time Frame for Submission
§158.135 Toxicology						
ACUTE TESTING						
81-1 - Acute Oral Toxicity	EP	All	No	-	Reserved 1/	
81-2 - Acute Dermal Toxicity	EP	All	No	-	Yes 1/, 2/	9 Month
81-3 - Acute Inhalation Toxicity	EP	All	No	-	Yes 1/, 2/	9 Month

1/ These data are required if the Toxicity Category I classification is challenged.

2/ In order to determine whether to impose restricted use classification, data are required on all end-use products. (These data will be waived if the registrants chooses to restrict the product and classify their products are Toxicity category I).

SUMMARY-1

LABEL CONTENTS

40 CFR 162.10 requires that certain specific labeling statements appear at certain locations on the label. This is referred to as format labeling. Specific label items listed below are keyed to the table at the end of this Appendix.

Item 1. PRODUCT NAME - The name, brand or trademark is required to be located on the front panel, preferably centered in the upper part of the panel. The name of a product will not be accepted if it is false or misleading.

Item 2. COMPANY NAME AND ADDRESS - The name and address of the registrant or distributor is required on the label. The name and address should preferably be located at the bottom of the front panel or at the end of the label text.

Item 3. NET CONTENTS - A net contents statement is required on all labels or on the container of the pesticide. The preferred location is the bottom of the front panel immediately above the company name and address, or at the end of the label text. The net contents must be expressed in the largest suitable unit, e.g., "1 pound 10 ounces" rather than "26 ounces." In addition to English units, net contents may be expressed in metric units. [40 CFR 162.10(d)]

Item 4. EPA REGISTRATION NUMBER - The registration number assigned to the pesticide product must appear on the label, preceded by the phrase "EPA Registration No.," or "EPA Reg. No." The registration number must be set in type of a size and style similar to other print on that part of the label on which it appears and must run parallel to it. The registration number and the required identifying phrase must not appear in such a manner as to suggest or imply recommendation or endorsement of the product by the Agency. [40 CFR 162.10(e)]

Item 5. EPA ESTABLISHMENT NUMBER - The EPA establishment number, preceded by the phrase "EPA Est." is the final establishment at which the product was produced, and may appear in any suitable location on the label or immediate container. It must also appear on the wrapper or outside container of the package if the EPA establishment number on the immediate container cannot be clearly read through such wrapper or container. [40 CFR 162.10(f)]

Item 6A. INGREDIENTS STATEMENT - An ingredients statement is required on the front panel. The ingredients statement must contain the name and percentage by weight of each active ingredient and the total percentage by weight of all inert ingredients. The preferred location is immediately below the product name. The ingredients statement must run parallel with, and be clearly distinguished from, other text on the panel. It must not be placed in the body of other text. [40 CFR 162.10(g)]

Item 6B. POUNDS PER GALLON STATEMENT - For liquid agricultural formulations, the pounds per gallon of active ingredient must be indicated on the label.

Item 7. FRONT LABEL PRECAUTIONARY STATEMENTS - Front panel precautionary statements must be grouped together, preferably within a block outline. The table below shows the minimum type size requirements for various size labels.

Size of Label on Front Panel in Square Inches	Signal Word Minimum Type Size All Capitals	"Keep Out of Reach of Children" Minimum Type Size
5 and under	6 point	6 point
above 5 to 10	10 point	6 point
above 10 to 15	12 point	8 point
above 15 to 30	14 point	10 point
over 30	18 point	12 point

Item 7A. CHILD HAZARD WARNING STATEMENT - The statement "Keep Out of Reach of Children" must be located on the front panel above the signal word except where contact with children during distribution or use is unlikely. [40 CFR 162.10(h)(1)(ii)]

Item 7B. SIGNAL WORD - The signal word (DANGER, WARNING, or CAUTION) is required on the front panel immediately below the child hazard warning statement. [40 CFR 162.10 (h)(1)(i)]

Item 7C. SKULL & CROSSBONES AND WORD "POISON" - On products assigned a toxicity Category I on the basis of oral, dermal, or inhalation toxicity, the word "Poison" shall appear on the label in red on a background of distinctly contrasting color and the skull and crossbones shall appear in immediate proximity to the word POISON. [40 CFR 162.10(h)(1)(i)]

Item 7D. STATEMENT OF PRACTICAL TREATMENT - A statement of practical treatment (first aid or other) shall appear on the label of pesticide products in toxicity Categories I, II, and III. [40 CFR 162.10(h)(1)(iii)]

Item 7E. REFERRAL STATEMENT - The statement "See Side (or Back) Panel for Additional Precautionary Statements" is required on the front panel for all products, unless all required precautionary statements appear on the front panel. [40 CFR 162.10(h)(1)(iii)]

Item 8. SIDE/BACK PANEL PRECAUTIONARY LABELING - The precautionary statements listed below must appear together on the label under the heading "PRECAUTIONARY STATEMENTS." The preferred location is at the top of the side or back panel preceding the directions for use, and it is preferred that these statements be surrounded by a block outline. Each of the three hazard warning statements must be headed by the appropriate hazard title. [40 CFR 162.10(h)(2)].

Item 8A. HAZARD TO HUMANS AND DOMESTIC ANIMALS - Where a hazard exists to humans or domestic animals, precautionary statements are required indicating the particular hazard, the route(s) of exposure and the precautions to be taken to avoid accident, injury or damage. [40 CFR 162.10(h)(2)(i)]

Item 8B. ENVIRONMENTAL HAZARD - Where a hazard exists to non-target organisms excluding humans and domestic animals, precautionary statements are required stating the nature of the hazard and the appropriate precautions to avoid potential accident, injury, or damage. [40 CFR 162.10(h)(2)(ii)]

Item 8C. PHYSICAL OR CHEMICAL HAZARD - FLAMMABILITY Precautionary statements relating to flammability of a product are required to appear on the label if it meets the criteria in the PHYS/CHEM Labeling Appendix. The requirement is based on the results of the flashpoint determinations and flame extension tests required to be submitted for all products. These statements are to be located in the side/back panel precautionary statements section, preceded by the heading "Physical/Chemical Hazards." Note that no signal word is used in conjunction with the flammability statements.

Item 9A. RESTRICTED USE CLASSIFICATION - FIFRA sec. 3(d) requires that all pesticide formulations/uses be classified for either general or restricted use. Products classified for restricted use may be limited to use by certified applicators or persons under their direct supervision (or may be subject to other restrictions that may be imposed by regulation).

In the Registration Standard, the Agency has (1) indicated certain formulations/uses are to be restricted (Section IV indicates why the product has been classified for restricted use); or (2) reserved any classification decision until appropriate data are submitted.

The Regulatory Position and Rationale states whether products containing this active ingredient are classified for restricted use. If they are restricted the draft label(s) submitted to the Agency as part of your application must reflect this determination (see below).

If you do not believe that your product should be classified for restricted use, you must submit any information and rationale with your application for reregistration. During the Agency's review of your application, your proposed classification determination will be evaluated in accordance with the provisions of 40 CFR 162.11(c). You will be notified of the Agency's classification decision.

Classification Labeling Requirements

If your product has been classified for restricted use, the following label requirements apply:

1. All uses restricted.

a. The statement "Restricted Use Pesticide" must appear at the top of the front panel of the label. The statement must be set in type of the same minimum size as required for human hazard signal word (see table in 40 CFR 162.10(h)(1)(iv)

b. Directly below this statement on the front panel, a summary statement of the terms of restriction must appear (including the reasons for restriction if specified in Section I). If use is restricted to certified applicators, the following statement is required: "For retail sale to and use only by Certified Applicators or persons under their direct supervision and only for those uses covered by the Certified Applicator's Certification."

2. Some but not all uses restricted. If the Regulatory Position and Rationale states that some uses are classified for restricted use, and some are unclassified, several courses of action are available:

a. You may label the product for Restricted use. If you do so, you may include on the label uses that are unrestricted, but you may not distinguish them on the label as being unrestricted.

b. You may delete all restricted uses from your label and submit draft labeling bearing only unrestricted uses.

c. You may "split" your registration, i.e., register two separate products with identical formulations, one bearing only unrestricted uses, and the other bearing restricted uses. To do so, submit two applications for reregistration, each containing all forms and necessary labels. Both applications should be submitted simultaneously. Note that the products will be assigned separate registration numbers.

Item 9B. MISUSE STATEMENT - All products must bear the misuse statement, "It is a violation of Federal law to use this product in a manner inconsistent with its labeling." This statement appears at the beginning of the directions for use, directly beneath the heading of that section.

SUMMARY-5

Item 10A. REENTRY STATEMENT - If a reentry interval has been established by the Agency, it must be included on the label. Additional worker protection statements may be required in accordance with PR Notice 83-2, March 29, 1983.

Item 10B. STORAGE AND DISPOSAL BLOCK - All labels are required to bear storage and disposal statements. These statements are developed for specific containers, sizes, and chemical content. These instructions must be grouped and appear under the heading "Storage and Disposal" in the directions for use. This heading must be set in the same type sizes as required for the child hazard warning. Refer to Appendix II, STOR, PEST/DIS, and CONT/DIS to determine the storage and disposal instructions appropriate for your products.

Item 10C. DIRECTIONS FOR USE - Directions for use must be stated in terms which can be easily read and understood by the average person likely to use or to supervise the use of the pesticide. When followed, directions must be adequate to protect the public from fraud and from personal injury and to prevent unreasonable adverse effects on the environment. [40 CFR 162.10]

COLLATERAL LABELING

Bulletins, leaflets, circulars, brochures, data sheets, flyers, or other written or graphic printed matter which is referred to on the label or which is to accompany the product are termed collateral labeling. Such labeling may not bear claims or representations that differ in substance from those accepted in connection with registration of the product. It should be made part of the response to this notice and submitted for review.

SUMMARY-6

LABELING REQUIREMENTS OF THE FIFRA, AS AMENDED

ITEM	LABEL ELEMENT	APPLICABILITY OF REQUIREMENT	PLACEMENT ON LABEL		COMMENTS
			REQUIRED	PREFERRED	
1	Product name	All products	Front panel	Center front panel	
2	Company name and address	All products	None	Bottom front panel or end of label text	If registrant is not the producer, must be qualified by "Packed for . . .," "Distributed by. . .," etc.
3	Net contents	All products	None	Bottom front panel or end of label text	May be in metric units in addition to U.S. units
4	EPA Reg. No.	All products	None	Front panel	Must be in similar type size and run parallel to other type.
5	EPA Est. No.	All products	None	Front panel, immediately before or following Reg. No.	May appear on the container instead of the label.
6A	Ingredients statement	All products	Front panel	Immediately following product name	Text must run parallel with other text on the panel.
6B	Pounds/gallon statement	Liquid products where dosage given as lbs. ai/unit area	Front panel	Directly below the main ingredients statement	
7	Front panel precautionary statements	All products	Front panel		All front panel precautionary statements must be grouped together, preferably blocked.
7A	Keep Out of Reach of Children (Child hazard warning)	All products	Front panel	Above signal word	Note type size requirements.
7B	Signal word	All products	Front panel	Immediately below child hazard warning	Note type size requirements.

ITEM	LABEL ELEMENT	APPLICABILITY OF REQUIREMENT	PLACEMENT ON LABEL		COMMENTS
			REQUIRED	PREFERRED	
7C	Skull & crossbones and word POISON (in red)	All products which are Category I based on oral, dermal, or inhalation toxicity	Front panel	Both in close proximity to signal word	
7D	Statement of Practical Treatment or First Aid	All products in Categories I, II, and III	Category I: Front panel unless referral statement is used. Others: Grouped with side panel precautionary statements.	Front panel for all.	
7E	Referral statement	All products where precautionary labeling appears on other than front panel.	Front panel		
8	Side/back panel precautionary statements	All products	None	Top or side of back panel preceding directions for use	Must be grouped under the headings in 8A, 8B, and 8C; preferably blocked.
8A	Hazards to humans and domestic animals	All products in Categories I, II, and III	None	Same as above	Must be preceded by appropriate signal word.
8B	Environmental hazards	All products	None	Same as above	Environmental hazards include bee caution where applicable.

SUMMARY-8

ITEM	LABEL ELEMENT	APPLICABILITY OF REQUIREMENT	PLACEMENT ON LABEL		COMMENTS
			REQUIRED	PREFERRED	
8C	Physical or chemical hazards	All pressurized products, others with flash points under 150°F	None	Same as above	Refer to Appendix II guide PHYS/CHEM
9A	Restricted block	All restricted products	Top center of front panel	Preferably blocked	Includes a statement of the terms of restriction. The words "RESTRICTED USE PESTICIDE" must be same type size as signal word.
9B	Misuse statement	All products	Immediately following heading of directions for use		Required statement is: "It is a violation of Federal law to use this product in a manner inconsistent with its labeling."
10A	Reentry statement	PR Notice 83-2 or as determined by the Agency	In the directions for use	Immediately after misuse statement	
10B	Storage and disposal block	All products	In the directions for use	Immediately before specific directions for use or at the end of directions for use	Must be set apart and clearly distinguishable from from other directions for use. Refer to Appendix II guides STOR, CONT/DIS, and PEST/DIS for further information and required statements.
10C	Directions for use	All products	None	None	May be in metric as well as U.S. units

~~cant obtained the data from another firm (identify); applicant copied data from a publication; applicant obtained a copy of the data from EPA).~~

~~(d) The applicant shall submit with his application a statement that EPA, in its evaluation of the properties, efficacy, and safety of the formulated end-use product, may not consider any data as supporting the application, except the following data:~~

~~(1) The data the applicant has submitted to EPA under paragraph (b) of this section;~~

~~(2) Other data pertaining to the safety of the product's active ingredients, rather than to the safety of the end-use product; and~~

~~(3) Existing tolerances, food additive regulations, exemptions, and other clearances issued under the Federal Food, Drug, and Cosmetic Act.~~

~~(e) If the applicant knows that any item of data he submitted under this section was generated by (or at the expense of) another person who originally submitted the data to EPA (or its predecessor, USDA) on or after January 1, 1970, to support an application for registration, experimental use permit, or amendment adding a new use to an existing registration, or for reregistration (unless the applicant and the original data submitter have reached written agreement on the amount and the terms of payment of any compensation that may be payable under FIFRA section 3(c)(1)(D)(ii) with regard to approval of the application), the applicant shall submit to EPA a statement that he has furnished to each such identified original data submitter:~~

~~(1) A notification of the applicant's intent to apply for registration, including the proposed product name;~~

~~(2) An offer to pay the person compensation, with regard to the approval of the application, to the extent required by FIFRA sections 3(c)(1)(D) and 3(c)(2)(D);~~

~~(3) An identification of the item(s) of data to which the offer applies;~~

~~(4) An offer to commence negotiations to ascertain the amount and terms of compensation to be paid; and~~

~~(5) The applicant's name, address, and telephone number.~~

~~(f) If the applicant's product contains any active ingredient other than those that are present solely because of the incorporation into the product, during formulation, of one or more other registered pesticide products purchased from another producer, then the applicant shall also comply with § 162.9-5 as to such active ingredient, and the application shall contain an acknowledgment that for purposes of FIFRA section 3(c)(1)(D) the application relies on (and any resulting registration should be regarded as if it were based on the Administrator's consideration of) the following data:~~

~~(1) All data submitted or specifically cited by the applicant in support of the registration; and~~

~~(2) Each other item of data in the Agency's files which:~~

~~(i) Concerns the properties or effects of any such active ingredient; and~~

~~(ii) Is one of the types of data that EPA would require to be submitted for scientific review by EPA if the applicant sought the initial registration under FIFRA Section 3(c)(5) of a product with composition and intended uses identical to those proposed for the applicant's product, under the data requirements in effect on the date EPA approves the applicant's present application.~~

(Secs. 3, 6, and 25 of FIFRA, as amended, 7 U.S.C. 136 *et seq.*)

[44 FR 27953, May 11, 1979]

§ 162.10 Labeling requirements.

(a) *General*—(1) *Contents of the label.* Every pesticide products shall bear a label containing the information specified by the Act and the regulations in this Part. The contents of a label must show clearly and prominently the following:

(i) The name, brand, or trademark under which the product is sold as prescribed in paragraph (b) of this section;

(ii) The name and address of the producer, registrant, or person for whom produced as prescribed in paragraph (c) of this section;

(iii) The net contents as prescribed in paragraph (d) of this section;

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(continued)

(iv) The product registration number as prescribed in paragraph (e) of this section;

(v) The producing establishment number as prescribed in paragraph (f) of this section;

(vi) An ingredient statement as prescribed in paragraph (g) of this section;

(vii) Warning or precautionary statements as prescribed in paragraph (h) of this section;

(viii) The directions for use as prescribed in paragraph (i) of this section; and

(ix) The use classification(s) as prescribed in paragraph (j) of this section.

(2) *Prominence and legibility.* (i) All words, statements, graphic representations, designs or other information required on the labeling by the Act or the regulations in this part must be clearly legible to a person with normal vision, and must be placed with such conspicuousness (as compared with other words, statements, designs, or graphic matter on the labeling) and expressed in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use.

(ii) All required label text must:

(A) Be set in 6-point or larger type;

(B) Appear on a clear contrasting background; and

(C) Not be obscured or crowded.

(3) *Language to be used.* All required label or labeling text shall appear in the English language. However, the Agency may require or the applicant may propose additional text in other languages as is considered necessary to protect the public. When additional text in another language is necessary, all labeling requirements will be applied equally to both the English and other-language versions of the labeling.

(4) *Placement of Label*—(i) *General.* The label shall appear on or be securely attached to the immediate container of the pesticide product. For purposes of this Section, and the misbranding provisions of the Act, "securely attached" shall mean that a label can reasonably be expected to remain affixed during the foreseeable conditions and period of use. If the immediate container is enclosed within a wrapper or outside container through which the label cannot be clearly read, the label must also be securely attached to such outside wrapper or container, if it is a part of the package as customarily distributed or sold.

(ii) *Tank cars and other bulk containers*—(A) *Transportation.* While a pesticide product is in transit, the appropriate provisions of 49 CFR Parts 170-189, concerning the transportation of hazardous materials, and specifically those provisions concerning the labeling, marking and placarding of hazardous materials and the vehicles carrying them, define the basic Federal requirements. In addition, when any registered pesticide product is transported in a tank car, tank truck or other mobile or portable bulk container, a copy of the accepted label must be attached to the shipping papers, and left with the consignee at the time of delivery.

(B) *Storage.* When pesticide products are stored in bulk containers, whether mobile or stationary, which remain in the custody of the user, a copy of the label of labeling, including all appropriate directions for use, shall be securely attached to the container in the immediate vicinity of the discharge control valve.

(5) *False or misleading statements.* Pursuant to section 2(q)(1)(A) of the Act, a pesticide or a device declared subject to the Act pursuant to § 162.15, is misbranded if its labeling is false or misleading in any particular including both pesticidal and non-pesticidal claims. Examples of statements or representations in the labeling which constitute misbranding include:

(i) A false or misleading statement concerning the composition of the product;

(ii) A false or misleading statement concerning the effectiveness of the product as a pesticide or device;

(iii) A false or misleading statement about the value of the product for purposes other than as a pesticide or device;

(iv) A false or misleading comparison with other pesticides or devices;

(v) Any statement directly or indirectly implying that the pesticide or device is recommended or endorsed by any agency of the Federal Government;

(vi) The name of a pesticide which contains two or more principal active ingredients if the name suggests one or more but not all such principal active ingredients even though the names of the other ingredients are stated elsewhere in the labeling;

(vii) A true statement used in such a way as to give a false or misleading impression to the purchaser;

(viii) Label disclaimers which negate or detract from labeling statements required under the Act and these regulations;

(ix) Claims as to the safety of the pesticide or its ingredients, including statements such as "safe," "nonpoisonous," "noninjurious," "harmless" or "nontoxic to humans and pets" with or without such a qualifying phrase as "when used as directed"; and

(x) Non-numerical and/or comparative statements on the safety of the product, including but not limited to:

(A) "Contains all natural ingredients";

(B) "Among the least toxic chemicals known"

(C) "Pollution approved"

(6) *Final printed labeling.* (i) Except as provided in paragraph (a)(6)(ii) of this section, final printed labeling must be submitted and accepted prior to registration. However, final printed labeling need not be submitted until draft label texts have been provisionally accepted by the Agency.

(ii) Clearly legible reproductions or photo reductions will be accepted for unusual labels such as those silk-screened directly onto glass or metal containers or large bag or drum labels. Such reproductions must be of microfilm reproduction quality.

(b) *Name, brand, or trademark.* (1) The name, brand, or trademark under which the pesticide product is sold shall appear on the front panel of the label.

(2) No name, brand, or trademark may appear on the label which:

(i) Is false or misleading, or

(ii) Has not been approved by the Administrator through registration or supplemental registration as an additional name pursuant to § 162.6(b)(4).

(c) Name and address of producer, registrant, or person for whom produced. An unqualified name and address given on the label shall be considered as the name and address of the producer. If the registrant's name appears on the label and the registrant is not the producer, or if the name of the person for whom the pesticide was produced appears on the label, it must be qualified by appropriate wording such as "Packed for * * *," "Distributed by * * *," or "Sold by * * *" to show that the name is not that of the producer.

(d) *Net weight or measure of contents.* (1) The net weight or measure of content shall be exclusive of wrappers or other materials and shall be the average content unless explicitly stated as a minimum quantity.

(2) If the pesticide is a liquid, the net content statement shall be in terms of liquid measure at 68° F (20°C) and shall be expressed in conventional American units of fluid ounces, pints, quarts, and gallons.

(3) If the pesticide is solid or semisolid, viscous or pressurized, or is a mixture of liquid and solid, the net content statement shall be in terms of weight expressed as avoirdupois pounds and ounces.

(4) In all cases, net content shall be stated in terms of the largest suitable units, i.e., "1 pound 10 ounces" rather than "26 ounces."

(5) In addition to the required units specified, net content may be expressed in metric units.

(6) Variation above minimum content or around an average is permissible only to the extent that it represents deviation unavoidable in good manufacturing practice. Variation below a stated minimum is not permitted. In no case shall the average content of the packages in a shipment fall below the stated average content.

(e) *Product registration number.* The registration number assigned to the pesticide product at the time of registration shall appear on the label, preceded by the phrase "EPA Registration No.," or the phrase "EPA Reg. No." The registration number shall be set in type of a size and style similar to other print on that part of the label on which it appears and shall run parallel to it. The registration number and the required identifying phrase shall not appear in such a manner as to suggest or imply recommendation or endorsement of the product by the Agency.

(f) *Producing establishments registration number.* The producing establishment registration number preceded by the phrase "EPA Est.", of the final establishment at which the product was produced may appear in any suitable location on the label or immediate container. It must appear on the wrapper or outside container of the package if the EPA establishment registration number on the immediate container cannot be clearly read through such wrapper or container.

(g) *Ingredient statement*—(1) *General.* The label of each pesticide product must bear a statement which contains the name and percentage by weight of each active ingredient, the total percentage by weight of all inert ingredients; and if the pesticide contains arsenic in any form, a statement of the percentages of total and water-soluble arsenic calculated as elemental arsenic. The active ingredients must be designated by the term "active ingredients" and the inert ingredients by the term "inert ingredients," or the singular forms of these terms when appropriate. Both terms shall be in the same type size, be aligned to the same margin and be equally prominent. The statement "Inert ingredients, none" is not required for pesticides which contain 100 percent active ingredients. Unless the ingredient statement is a complete analysis of the pesticide, the term "analysis" shall not be used as a heading for the ingredient statement.

(2) *Position of ingredient statement.* (i) The ingredient statement is normally required on the front panel of the label. If there is an outside container or wrapper through which the ingredient statement cannot be clearly read, the ingredient statement must also appear on such outside container or wrapper. If the size or form of the package makes it impracticable to place the ingredient statement on the front panel of the label, permission may be granted for the ingredient statement to appear elsewhere.

(ii) The text of the ingredient statement must run parallel with other text on the panel on which it appears, and must be clearly distinguishable from and must not be placed in the body of other text.

(3) *Names to be used in ingredient statement.* The name used for each ingredient shall be the accepted common name, if there is one, followed by the chemical name. The common name may be used alone only if it is well known. If no common name has been established, the chemical name alone shall be used. In no case will the use of a trademark or proprietary name be permitted unless such name has been accepted as a common name by the Administrator under the authority of Section 25(c)(6).

(4) *Statements of percentages.* The percentages of ingredients shall be stated in terms of weight-to-weight. The sum of percentages of the active and the inert ingredients shall be 100. Percentages shall not be expressed by a range of values such as "22-25%." If the uses of the pesticide product are expressed as weight of active ingredient per unit area, a statement of the weight of active ingredient per unit volume of the pesticide formulation shall also appear in the ingredient statement.

(5) *Accuracy of stated percentages.* The percentages given shall be as precise as possible reflecting good manufacturing practice. If there may be unavoidable variation between manufacturing batches, the value stated for each active ingredient shall be the lowest percentage which may be present.

(6) *Deterioration.* Pesticides which change in chemical composition significantly must meet the following labeling requirements:

(i) In cases where it is determined that a pesticide formulation changes chemical composition significantly, the product must bear the following statement in a prominent position on the label: "Not for sale or use after [date]."

(ii) The product must meet all label claims up to the expiration time indicated on the label.

(7) *Inert ingredients.* The Administrator may require the name of any inert ingredient(s) to be listed in the ingredient statement if he determines that such ingredient(s) may pose a hazard to man or the environment.

(h) *Warnings and precautionary statements.* Required warnings and precautionary statements concerning the general areas of toxicological hazard including hazard to children, environmental hazard, and physical or chemical hazard fall into two groups; those required on the front panel of the labeling and those which may appear elsewhere. Specific requirements concerning content, placement, type size, and prominence are given below.

(1) *Required front panel statements.* With the exception of the child hazard warning statement, the text required on the front panel of the label is determined by the Toxicity Category of the pesticide. The category is assigned on the basis of the highest hazard shown by any of the indicators in the table below:

Hazard indicators	Toxicity categories			
	I	II	III	IV
Oral LD_{50}	Up to and including 50 mg/kg	From 50 thru 500 mg/kg	From 500 thru 5000 mg/kg	Greater than 5000 mg/kg
Inhalation LC_{50}	Up to and including .2 mg/liter	From .2 thru 2 mg/liter	From 2 thru 20 mg/liter	Greater than 20 mg/liter
Dermal LD_{50}	Up to and including 200 mg/kg	From 200 thru 2000	From 2,000 thru 20,000	Greater than 20,000
Eye effects	Corrosive; corneal opacity not reversible within 7 days	Corneal opacity reversible within 7 days; irritation persisting for 7 days	No corneal opacity; irritation reversible within 7 days	No irritation
Skin effects	Corrosive	Severe irritation at 72 hours.	Moderate irritation at 72 hours	Mild or slight irritation at 72 hours

(i) *Human hazard signal word*—(A) *Toxicity Category I.* All pesticide products meeting the criteria of Toxicity Category I shall bear on the front panel the signal word "Danger." In addition if the product was assigned to Toxicity Category I on the basis of its oral, inhalation or dermal toxicity (as distinct from skin and eye local effects) the word "Poison" shall appear in red on a background of distinctly contrasting color and the skull and crossbones shall appear in immediate proximity to the word "poison."

(B) *Toxicity Category II.* All pesticide products meeting the criteria of Toxicity Category II shall bear on the front panel the signal word "Warning."

(C) *Toxicity Category III.* All pesticide products meeting the criteria of Toxicity Category III shall bear on the front panel the signal word "Caution."

(D) *Toxicity Category IV.* All pesticide products meeting the criteria of Toxicity Category IV shall bear on the front panel the signal word "Caution."

(E) *Use of signal words.* Use of any signal word(s) associated with a higher Toxicity Category is not permitted except when the Agency determines that such labeling is necessary to prevent unreasonable adverse effects on man or the environment. In no case shall more than one human hazard signal word appear on the front panel of a label.

(ii) *Child hazard warning.* Every pesticide product label shall bear on the front panel the statement "keep out of reach of children." Only in cases where the likelihood of contact with children during distribution, marketing, storage or use is demonstrated by the applicant to be extremely remote, or if the nature of the pesticide is such that it is approved for use on infants or small children, may the Administrator waive this requirement.

(iii) *Statement of practical treatment*—(A) *Toxicity Category I.* A statement of practical treatment (first aid or other) shall appear on the front panel of the label of all pesticides falling into Toxicity Category I on the basis of oral, inhalation or dermal toxicity. The Agency may, however, permit reasonable variations in the placement of the statement of practi-

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(continued)

cal treatment is some reference such as "See statement of practical treatment on back panel" appears on the front panel near the word "Poison" and the skull and crossbones.

(B) *Other toxicity categories.* The statement of practical treatment is not required on the front panel except as described in paragraph (h)(1)(iii)(A) of this section. The applicant may, however, include such a front panel statement at his option. Statements of practical treatment are, however, required elsewhere on the label in accord with paragraph (h)(2) of this section if they do not appear on the front panel.

(iv) *Placement and prominence.* All the require front panel warning statements shall be grouped together on the label, and shall appear with sufficient prominence relative to other front panel text and graphic material to make them unlikely to be overlooked under customary conditions of purchase and use. The following table shows the minimum type size requirements for the front panel warning statements on various sizes of labels:

Size of label front panel in square inches	Points	
	Required signal word, all capitals	"Keep out of reach of Children"
5 and under	6	6
Above 5 to 10	10	6
Above 10 to 15	12	8
Above 15 to 30	14	10
Over 30	18	12

(2) *Other required warnings and precautionary statements.* The warnings and precautionary statements as required below shall appear together on the label under the general heading "Precautionary Statements" and under appropriate subheadings of "Hazard to Humans and Domestic Animals," "Environmental Hazard" and "Physical or Chemical Hazard."

(i) *Hazard to humans and domestic animals.* (A) Where a hazard exists to humans or domestic animals, precautionary statements are required indicating the particular hazard, the route(s) of exposure and the precautions to be taken to avoid accident, injury or damage. The precautionary paragraph shall be immediately preceded by the appropriate hazard signal word.

(B) The following table depicts typical precautionary statements. These statements must be modified or expanded to reflect specific hazards.

Toxicity category	Precautionary statements by toxicity category	
	Oral, inhalation, or dermal toxicity	Skin and eye local effects
I	Fatal (poisonous) if swallowed [inhaled or absorbed through skin]. Do not breathe vapor [dust or spray mist]. Do not get in eyes, on skin, or on clothing [Front panel statement of practical treatment required.].	Corrosive, causes eye and skin damage [or skin irritation]. Do not get in eyes, on skin, or on clothing. Wear goggles or face shield and rubber gloves when handling. Harmful or fatal if swallowed. [Appropriate first aid statement required.]
II	May be fatal if swallowed [inhaled or absorbed through the skin]. Do not breathe vapors [dust or spray mist]. Do not get in eyes, on skin, or on clothing. [Appropriate first aid statements required.].	Causes eye [and skin] irritation. Do not get in eyes, on skin, or on clothing. Harmful if swallowed. [Appropriate first aid statement required.]
III	Harmful if swallowed [inhaled or absorbed through the skin]. Avoid breathing vapors [dust or spray mist]. Avoid contact with skin [eyes or clothing]. [Appropriate first aid statement required.].	Avoid contact with skin, eyes or clothing. In case of contact immediately flush eyes or skin with plenty of water. Get medical attention if irritation persists.
IV	[No precautionary statements required.]	[No precautionary statements required.]

(ii) *Environmental hazards.* Where a hazard exists to non target organisms excluding humans and domestic animals, precautionary statements are required stating the nature of the hazard and the appropriate precautions to avoid potential accident, injury or damage. Examples of the hazard statements and the circumstances under which they are required follow:

(A) If a pesticide intended for outdoor use contains an active ingredient with a mammalian acute oral LD_{50} of 100 or less, the statement "This Pesticide is Toxic to Wildlife" is required.

(B) If a pesticide intended for outdoor use contains an active ingredient with a fish acute LC_{50} of 1 ppm or less, the statement "This Pesticide is Toxic to Fish" is required.

(C) If a pesticide intended for outdoor use contains an active ingredient with an avian acute oral LD_{50} of 100 mg/kg or less, or a subacute dietary LC_{50} of 500 ppm or less, the statement "This Pesticide is Toxic to Wildlife" is required.

(D) If either accident history or field studies demonstrate that use of the pesticide may result in fatality to birds, fish or mammals, the statement "This pesticide is extremely toxic to wildlife (fish)" is required.

(E) For uses involving foliar application to agricultural crops, forests, or shade trees, or for mosquito abatement treatments, pesticides toxic to pollinating insects must bear appropriate label cautions.

(F) For all outdoor uses other than aquatic applications the label must bear the caution "Keep out of lakes, ponds or streams. Do not contaminate water by cleaning of equipment or disposal of wastes."

(iii) *Physical or chemical hazards.* Warning statements on the flammability or explosive characteristics of the pesticide are required as follows:

Flash point	Required text
(A) PRESSURIZED CONTAINERS	
Flash point at or below 20° F; if there is a flashback at any valve opening	Extremely flammable. Contents under pressure. Keep away from fire, sparks, and heated surfaces. Do not puncture or incinerate container. Exposure to temperatures above 130° F may cause bursting.
Flash point above 20° F and not over 80° F or if the flame extension is more than 18 in long at a distance of 6 in from the flame	Flammable. Contents under pressure. Keep away from heat, sparks, and open flame. Do not puncture or incinerate container. Exposure to temperatures above 130° F may cause bursting.
All other pressurized containers	Contents under pressure. Do not use or store near heat or open flame. Do not puncture or incinerate container. Exposure to temperatures above 130° F may cause bursting.
(B) NONPRESSURIZED CONTAINERS	
At or below 20° F	Extremely flammable. Keep away from fire, sparks, and heated surfaces.
Above 20° F and not over 80° F	Flammable. Keep away from heat and open flame.
Above 80° F and not over 150° F	Do not use or store near heat or open flame.

(i) *Directions for Use*—(1) *General requirements*—(i) *Adequacy and clarity of directions.* Directions for use must be stated in terms which can be easily read and understood by the average person likely to use or to supervise the use of the pesticide. When followed, directions must be adequate to protect the public from fraud and from personal injury and to prevent unreasonable adverse effects on the environment.

(ii) *Placement of directions for use.* Directions may appear on any portion of the label provided that they are conspicuous enough to be easily read by the user of the pesticide product. Directions for use may appear on printed or graphic matter which accompanies the pesticide provided that:

(A) If required by the Agency, such printed or graphic matter is securely attached to each package of the pesticide, or placed within the outside wrapper or bag;

(B) The label bears a reference to the directions for use in accompanying leaflets or circulars, such as "See directions in the enclosed circular:" and

(C) The Administrator determines that it is not necessary for such directions to appear on the label.

(iii) *Exceptions to requirement for direction for use*—(A) Detailed directions for use may be omitted from labeling of pesticides which are intended for use only by manufacturers of products other than pesticide products in their regular manufacturing processes

(*1*) The label clearly shows that the product is intended for use only in manufacturing processes and specifies the type(s) of products involved.

(*2*) Adequate information such as technical data sheets or bulletins, is available to the trade specifying the type of product involved and its proper use in manufacturing processes;

(*3*) The product will not come into the hands of the general public except after incorporation into finished products; and

(*4*) The Administrator determines that such directions are not necessary to prevent unreasonable adverse effects on man or the environment.

(B) Detailed directions for use may be omitted from the labeling of pesticide products for which sale is limited to physicians, veterinarians, or druggists, provided that:

(*1*) The label clearly states that the product is for use only by physicians or veterinarians;

(*2*) The Administrator determines that such directions are not necessary to prevent unreasonable adverse effects on man or the environment; and

(*3*) The product is also a drug and regulated under the provisions of the Federal Food, Drug and Cosmetic Act.

(C) Detailed directions for use may be omitted from the labeling of pesticide products which are intended for use only by formulators in preparing pesticides for sale to the public, provided that:

(*1*) There is information readily available to the formulators on the composition, toxicity, methods of use, applicable restrictions or limitations, and effectiveness of the product for pesticide purposes;

(*2*) The label clearly states that the product is intended for use only in manufacturing, formulating, mixing, or repacking for use as a pesticide and specifies the type(s) of pesticide products involved;

(*3*) The product as finally manufactured, formulated, mixed, or repackaged is registered; and

(*4*) The Administrator determines that such directions are not necessary to prevent unreasonable adverse effects on man or the environment.

(3) *Contents of Directions for Use.* The directions for use shall include the following, under the headings "Directions for Use":

(i) The statement of use classification as prescribed in 162.10(j) immediately under the heading "Directions for Use."

(ii) Immediately below the statement of use classification, the statement "It is a violation of Federal law to use this product in a manner inconsistent with its labeling."

(iii) The site(s) of application, as for example the crops, animals, areas, or objects to be treated.

(iv) The target pest(s) associated with each site.

(v) The dosage rate associated with each site and pest.

(vi) The method of application, including instructions for dilution, if required, and type(s) of application apparatus or equipment required.

(vii) The frequency and timing of applications necessary to obtain effective results without causing unreasonable adverse effects on the environment.

(viii) Specific limitations on reentry to areas where the pesticide has been applied, meeting the requirements concerning reentry provided by 40 CFR Part 170.

(ix) Specific directions concerning the storage and disposal of the pesticide and its container, meeting the requirements of 40 CFR Part 165. These instructions shall be grouped and appear under the heading "Storage and Disposal." This heading must be set in type of the same minimum sizes as required for the child hazard warning (See Table in § 162.10(h)(1)(iv).)

(x) Any limitations or restrictions on use required to prevent unreasonable adverse effects, such as:

(A) Required intervals between application and harvest of food or feed crops.

(B) Rotational crop restrictions.

(C) Warnings as required against use on certain crops, animals, objects, or in or adjacent to certain areas.

(D) [Reserved]

(E) For restricted use pesticides, a statement that the pesticide may be applied under the direct supervision of a certified applicator who is not physically present at the site of application but nonetheless available to the person applying the pesticide, unless the Agency has determined that the pesticide may only be applied under the direct supervision of a certified applicator who is physically present.

(F) Other pertinent information which the Administrator determines to be necessary for the protection of man and the environment.

(j) *Statement of Use Classification.* By October 22, 1976, all pesticide products must bear on their labels a statement of use classification as described in paragraphs (j)(1) and (2) of this section. Any pesticide product for which some uses are classified for general use and others for restricted use shall be separately labeled according to the labeling standards set forth in this subsection, and shall be marketed as separate products with different registration numbers, one bearing directions only for general use(s) and the other bearing directions for restricted use(s) except that, if a product has both restricted use(s) and general use(s), both of these uses may appear on a product labeled for restricted use. Such products shall be subject to the provisions of § 162.10(j)(2).

(1) *General Use Classification.* Pesticide products bearing directions for use(s) classified general shall be labeled with the exact words "General Classification" immediately below the heading "Directions for Use." And reference to the general classification that suggests or implies that the general utility of the pesticide extends beyond those purposes and uses contained in the Directions for Use will be considered a false or misleading statement under the statutory definitions of misbranding.

(2) *Restricted Use Classification.* Pesticide products bearing direction for use(s) classified restricted shall bear statements of restricted use classification on the front panel as described below:

(i) *Front panel statement of restricted use classification.* (A) At the top of the front panel of the label, set in type of the same minimum sizes as required for human hazard signal words (see table in § 162.10(h)(1)(iv)), and appearing with sufficient prominence relative to other text and graphic material on the front panel to make it unlikely to be overlooked under customary conditions of purchase and use, the statement "Restricted Use Pesticide" shall appear.

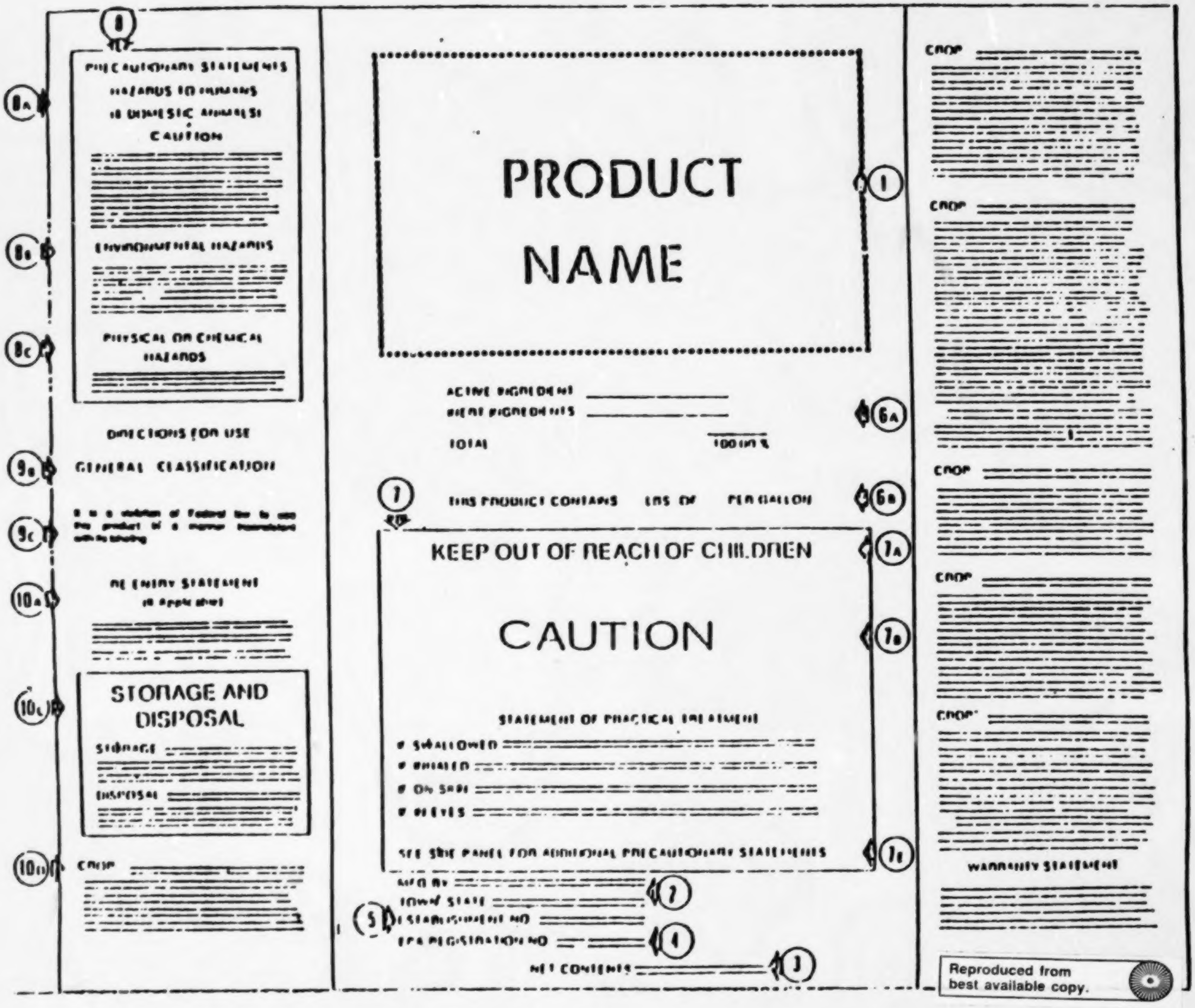
(B) Directly below this statement on the front panel, a summary statement of the terms of restriction imposed as a precondition to registration shall appear. If use is restricted to certified applicators, the following statement is required: "For retail sale to and use only by Certified Applicators or persons under their direct supervision and only for those uses covered by the Certified Applicator's certification." If, however, other regulatory restrictions are imposed, the Administrator will define the appropriate wording for the terms of restriction by regulation.

(k) *Advertising.* [Reserved]

[40 FR 28268, July 3, 1975; 40 FR 32329, Aug. 1, 1975; 40 FR 36571, Aug. 21, 1975, as amended at 43 FR 5786, Feb. 9, 1978]

~~§ 162.11 Criteria for determinations of unreasonable adverse effects.~~

~~(a) *Criteria for Issuance of Notice of Intent to Deny Registration, Cancel Registration, or to Hold a Hearing*—(1) *Presumption.* (i) A rebuttable presumption shall arise that a notice of intent to deny registration pursuant to section 3(c)(6) of the Act, a notice of intent to cancel registration pursuant to section 6(b)(1) of the Act, or a notice of intent to hold a hearing to determine whether the registration should be cancelled or denied, as appropriate, shall be issued, upon a determination by the Administrator that the pesticide meets or exceeds any of the criteria for risk set forth in paragraph (a)(3) of this section. Upon such determination, the Administrator shall issue notice by certified mail to the applicant or registrant, as the case may be, stating that the applicant or registrant has the opportunity to submit evidence in rebuttal of such presumption in accordance with paragraph (a)(4) of this section. The applicant or registrant shall have forty-five (45) days from the date such notice is sent to submit evidence in rebuttal of the presumption; provided, however, that for good cause shown the Administrator may grant an additional sixty~~


1
PRODUCT NAME
6A
ACTIVE INGREDIENT
INERT INGREDIENTS
TOTAL
100.00%
6B
THIS PRODUCT CONTAINS LBS OF PER GALLON
7
7A
KEEP OUT OF REACH OF CHILDREN
7B
CAUTION
STATEMENT OF PRACTICAL TREATMENT
IF SWALLOWED
IF INHALED
IF ON SKIN
IF IN EYES
7C
SEE SIDE PANEL FOR ADDITIONAL PRECAUTIONARY STATEMENTS
2
MFD BY
TOWN, STATE
5
ESTABLISHMENT NO
4
EPA REGISTRATION NO
3
NET CONTENTS
8
8A
PRECAUTIONARY STATEMENTS
HAZARDS TO HUMANS
(& DOMESTIC ANIMALS)
CAUTION
8B
ENVIRONMENTAL HAZARDS
8C
PHYSICAL OR CHEMICAL HAZARDS
DIRECTIONS FOR USE
9B
GENERAL CLASSIFICATION
9C
It is a violation of Federal law to use this product in a manner inconsistent with its labeling
10A
RE-ENTRY STATEMENT
(If Applicable)
10C
STORAGE AND DISPOSAL
STORAGE
DISPOSAL
10D
CROP
CROP
CROP
CROP
CROP
CROP
WARRANTY STATEMENT

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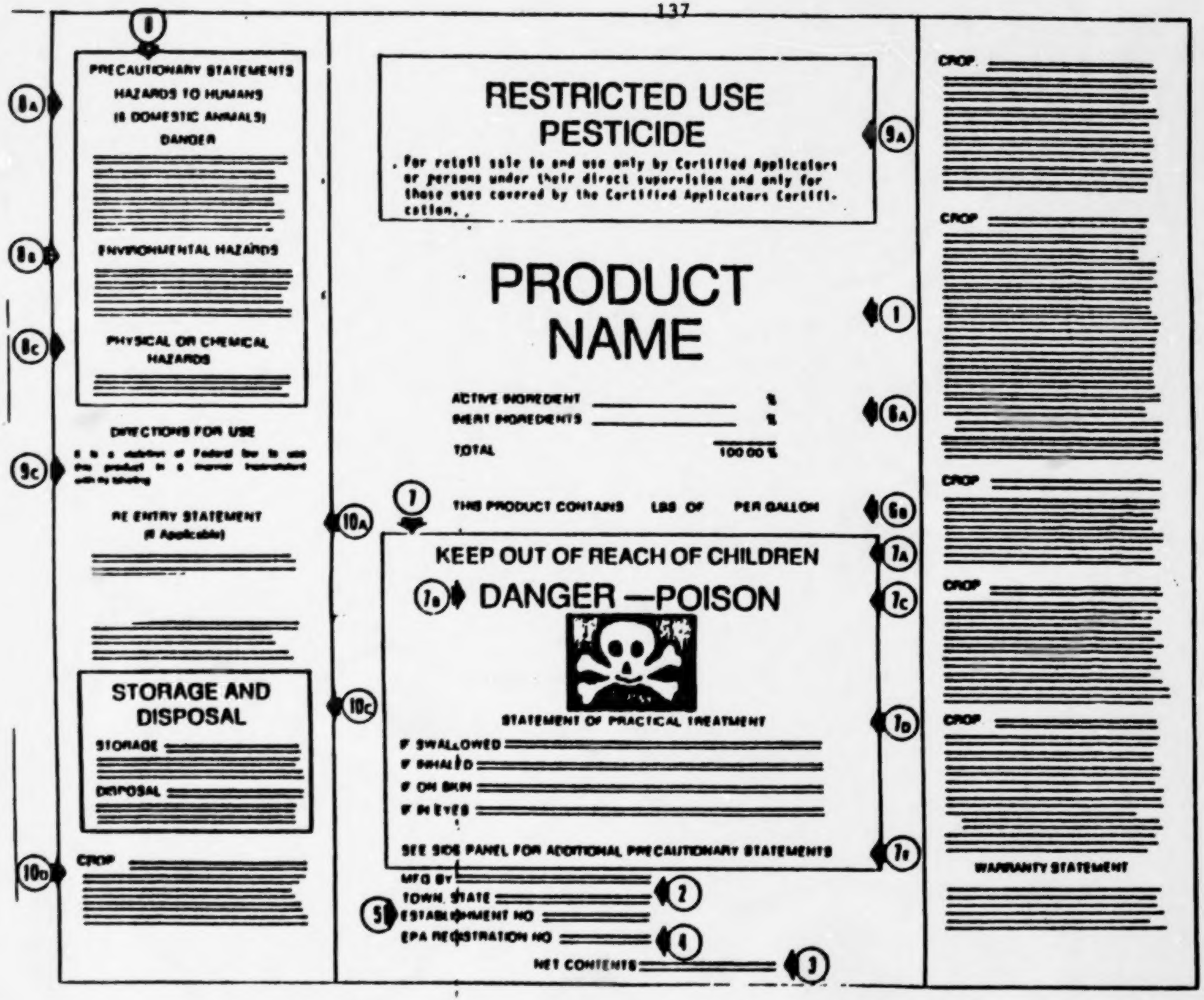

PRECAUTIONARY STATEMENTS
HAZARDS TO HUMANS
(& DOMESTIC ANIMALS)
DANGER

ENVIRONMENTAL HAZARDS

PHYSICAL OR CHEMICAL
HAZARDS

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling

RE ENTRY STATEMENT
(If Applicable)

STORAGE AND
DISPOSAL

STORAGE

DISPOSAL

CROP

RESTRICTED USE
PESTICIDE

For retail sale to and use only by Certified Applicators or persons under their direct supervision and only for those uses covered by the Certified Applicators Certification.

PRODUCT
NAME

ACTIVE INGREDIENT		%
INERT INGREDIENTS		%
TOTAL		100.00 %

THIS PRODUCT CONTAINS LBS OF PER GALLON

KEEP OUT OF REACH OF CHILDREN

DANGER —POISON

STATEMENT OF PRACTICAL TREATMENT

IF SWALLOWED
IF INHALED
IF ON SKIN
IF IN EYES

SEE SIDE PANEL FOR ADDITIONAL PRECAUTIONARY STATEMENTS

MFG BY
TOWN, STATE
ESTABLISHMENT NO
EPA REGISTRATION NO
NET CONTENTS

CROP

CROP

CROP

CROP

CROP

WARRANTY STATEMENT

PHYS/CHEM-1

PHYSICAL/CHEMICAL HAZARDS

Criteria	Required Label Statement
I. Pressurized Containers	
A. Flashpoint at or below 20°F; or if there is a flashback at any valve opening.	Extremely flammable. Contents under pressure. Keep away from fire, sparks, and heated surfaces. Do not puncture or incinerate container. Exposure to temperatures above 130°F may cause bursting.
B. Flashpoint above 20°F and not over 80°F; or if the flame extension is more than 18 inches long at a distance of 6 inches from the valve opening.	Flammable. Contents under pressure. Keep away from heat, sparks, and flame. Do not puncture or incinerate container. Exposure to temperatures above 130°F may cause bursting.
C. All Other Pressurized Containers	Contents under pressure. Do not use or store near heat or open flame. Do not puncture or incinerate container. Exposure to temperatures above 130°F may cause bursting.
II. Non-Pressurized Containers	
A. Flashpoint at or below 20°F.	Extremely flammable. Keep away from fire, sparks, and heated surfaces.
B. Flashpoint above 20°F and not over 80°F.	Flammable. Keep away from heat and open flame.
C. Flashpoint over 80°F and not over 150°F.	Do not use or store near heat and open flame.
D. Flashpoint above 150°F.	None required.

STOR-1

STORAGE INSTRUCTIONS FOR PESTICIDES

Heading:

All products are required to bear specific label instructions about storage and disposal. Storage and disposal instructions must be grouped together in the directions for use portion of the label under the heading STORAGE AND DISPOSAL. Products intended solely for domestic use need not include the heading "STORAGE AND DISPOSAL."

Storage Instructions:

All product labels are required to have appropriate storage instructions. Specific storage instructions are not prescribed. Each registrant must develop his own storage instructions, considering, when applicable, the following factors:

1. Conditions of storage that might alter the composition or usefulness of the pesticide. Examples could be temperature extremes, excessive moisture or humidity, heat, sunlight, friction, or contaminating substances or media.

2. Physical requirements of storage which might adversely affect the container of the product and its ability to continue to function properly. Requirements might include positioning of the container in storage, storage or damage due to stacking, penetration of moisture, and ability to withstand shock or friction.

3. Specifications for handling the pesticide container, including movement ot container within the storage area, proper opening and closing procedures (particularly for opened containers), and measures to minimize exposure while opening or closing container.

4. Instructions on what to do if the container is damaged in any way, or if the pesticide is leaking or has been spilled, and precautions to minimize exposure if damage occurs.

5. General precautions concerning locked storage, storage in original container only, and separation of pesticides during storage to prevent cross-contamination of other pesticides, fertilizer, food, and feed.

6. General storage instructions for household products should emphasize storage in original container and placement in locked storage areas.

PESTICIDE DISPOSAL INSTRUCTIONS

The label of all products, except those intended solely for domestic use, must bear explicit instructions about pesticide disposal. The statements listed below contain the exact wording that must appear on the label of these products:

1. The labels of all products, except domestic use, must contain the statement, "Do not contaminate water, food, or feed by storage or disposal."

2. Except those products intended solely for domestic use, the labels of all products that contain active ingredients that are Acute Hazardous Wastes (see list in this Appendix) or are assigned to Toxicity Category I on the basis of oral or dermal toxicity, skin or eye irritation potential, or Toxicity Category I or II on the basis of acute inhalation toxicity must bear the following pesticide disposal statement:

> "Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance."

3. The labels of all products, except those intended for domestic use, containing active or inert ingredients that are Toxic Hazardous Wastes (see list in this Appendix) or meet any of the criteria in 40 CFR 261, Subpart C for a hazardous waste must bear the following pesticide disposal statement:

> "Pesticide wastes are toxic. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance."

4. Labels for all other products, except those intended for domestic use, must bear the following pesticide disposal statement:

> "Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility."

5. Products intended for domestic use only must bear the following disposal statement: "Securely wrap original container in several layers of newspaper and discard in trash."

PESTICIDE ACTIVE INGREDIENTS THAT ARE ACUTE HAZARDOUS WASTES

I. PESTICIDES ON THE "E" LIST (with RCRA # and CAS #) [40 CFR 261.33(e)]

Acrolein	P003	107-13-1
Aldicarb	P070	116-06-3
Aldrin	P004	309-00-2
Allyl alcohol	P005	107-18-6
Aluminum phosphide	P006	1302-45-0
4-Aminopyridine (Avitrol)	P008	504-24-5
Arsenic acid	P010	7778-39-4
Arsenic pentoxide	P011	1303-28-2
Arsenic trioxide	P012	1327-53-3
Calcium cyanide	P021	592-01-8
Carbon disulfide	P022	75-15-0
p-Chloroaniline	P024	106-47-8
Cyanides (soluble cyanide salts not otherwise specified)	P030	
Cyanogen chloride	P031	506-77-4
Dieldrin	P037	60-57-1
O,O-Diethyl S-[2-ethylthio)ethyl] phosphorodithioate (disulfoton)	P039	298-04-4
O,O-Diethyl O-pyrazinyl phosphorothioate (Zinophos®)	P040	297-97-2
Dimethoate	P044	60-51-5
O,O-Dimethyl O-p-nitrophenyl phosphorothioate (methyl parathion)	P071	298-00-0
4,6-Dinitro-o-cresol and salts	P047	534-52-1
4,6-Dinitro-o-cyclohexylphenol	P034	131-89-5
Dinoseb	P020	88-85-7
Endosulfan	P050	115-29-7
Endothall	P088	129-67-9
Endrin	P051	72-20-8
Famphur	P097	52-85-7
Fluoroacetamide	P057	640-19-7
Heptachlor	P059	76-48-8
Hexachlorohexahydro-exo,exo-dimethanonaphthalene (Isodrin)	P069	465-73-6
Hydrocyanic acid	P063	74-90-8
Methomyl	P066	16752-77-5
alpha-Naphthylthiourea (ANTU)	P072	86-88-41
Nicotine and salts	P075	54-11-5
Octamethylpyrophosphoramide (OMPA, schradan)	P085	152-16-9
Parathion	P089	56-38-2
Phenylmercuric acetate (PMA)	P092	62-38-4
Phorate	P094	298-02-2
Potassium cyanide	P098	151-50-8
Propargyl alcohol	P102	107-19-7
Sodium azide	P105	26628-22-8
Sodium cyanide	P106	143-33-9
Sodium fluoroacetate	P058	62-74-8

Strychnine and salts	P108	57-24-9 60-41-3
O,O,O,O-Tetraethyl dithiopyrophosphate (sulfotepp)	P109	3689-24-5
Tetraethyl pyrophosphate	P111	107-49-3
Thallium sulfate	P115	7446-18-6
Thiofanox	P045	39196-18-4
Toxaphene	P123	8001-35-2
Warfarin (>0.3%)	P001	81-81-2
Zinc phosphide (>10%)	P122	1314-84-7

50 ACTIVES

II. PESTICIDES DERIVED FROM TRI-, TETRA-, AND PENTACHLOROPHENOLS [40 CFR 261.31]

2-Chloroethyl 2-(2,4,6-trichlorophenoxy) ethyl ether	F027	5324-22-1
Dehydroabietylammonium pentachlorophenoxide	F027	35109-57-0
Erbon	F027	136-25-4
O-ethyl O-(2,4,5-trichlorophenyl) ethylphosphonothioate	F027	327-98-0
2,2'-Methylenebis (3,4,6-trichlorophenol) (Hexachlorophene)	F027	70-30-4
--Potassium salt of	F027	67923-62-0
--Sodium salt of	F027	3247-34-5
--Disodium salt of	F027	5736-15-2
Pentachlorophenol	F027	87-86-5
--Potassium salt of	F027	7778-73-6
--Sodium salt of	F027	131-52-2
--Zinc salt of	F027	2917-32-0
--Zinc salt of N-alkyl (C_{16}-C_{18})-1,3-propanediamine	F027	
--Pentachlorophenyl laurate	F027	3772-94-9
Potassium trichlorophenate (2,4,6)	F027	2591-21-1
Potassium trichlorophenate (2,4,5)	F027	35471-43-3
Silvex	F027	93-72-1
--2-Butoxyethyl ester	F027	19398-13-1
--Butoxypolypropoxypropyl ester	F027	53404-07-2
--Butoxypropyl ester	F027	25537-26-2
--Diethanolamine salt	F027	51170-59-3
--Diisopropanolamine salt	F027	53404-09-4
--Dimethylamine salt	F027	55617-85-1
--Dipropylene glycol isobutyl ether ester	F027	53535-26-5
--Ethanolamine salt	F027	7374-47-2
--2-Ethylhexyl ester	F027	53404-76-5
--Isooctyl ester	F027	53404-14-1

--Isopropanolamine salt	F027	53404-13-0
--Monohydroxylaluminum salt	F027	69622-82-8
--Polypropoxypropyl ester	F027	83562-66-7
--Potassium salt	F027	2818-16-8
--Propylene glycol isobutyl ether ester	F027	53466-84-5
--Sodium salt	F027	37913-89-6
--Triethanolamine salt	F027	17369-89-0
--Triethylamine salt	F027	53404-74-3
--Triisopropanolamine salt	F027	53404-75-4
--Tripropylene glycol isobutyl ether ester	F027	53535-30-1
Sodium 2-(2,4,5-trichlorophenoxy) ethyl sulfate	F027	3570-61-4
Tetrachlorophenols	F027	25167-83-3
--Alkylamine*amine salt (as in fatty acids of coconut oil)	F027	
--Potassium salt	F027	53535-27-6
--Sodium salt	F027	25567-55-9
2,4,5-Trichlorophenol	F027	95-95-4
2,4,6-Trichlorophenol	F027	88-06-2
2,4,5-Trichlorophenol salt of 2,6-bis[(dimethylamino)methyl] cyclohexanone	F027	53404-83-4
2,4,5-Trichlorophenol, sodium salt	F027	136-32-3
2,4,6-Trichlorophenol, sodium salt	F027	3784-03-0
2,4,5-Trichlorophenoxyacetic acid	F027	93-79-8
--Alkyl C-12 amine salt	F027	53404-84-5
--Alkyl C-13 amine salt	F027	53404-85-6
--Alkyl C-14 amine salt	F027	53535-37-8
--N,N-diethylethanolamine salt	F027	53404-86-7
--Dimethylamine salt	F027	6369-97-7
--N,N-dimethyllinoleylamine salt	F027	53404-88-9
--N,N-dimethyloleylamine salt	F027	53404-89-0
--N-oleyl-1,3-propylene diamine salt	F027	53404-87-8
--Sodium salt	F027	13560-99-1
--Triethanolamine salt	F027	3813-14-7
--Triethylamine salt	F027	2008-46-0
--Alkyl (C3H7 - C7H9) ester	F027	
--Amyl ester	F027	120-39-8
--Butoxyethoxypropyl ester	F027	1928-58-1
--2-Butoxyethyl ester	F027	2545-59-7
--Butoxypropyl ester	F027	1928-48-9
--Butyl ester	F027	93-79-8
--Dipropylene glycol isobutyl ether ester	F027	53535-31-2
--2-Ethylhexyl ester	F027	1928-47-8
--Isobutyl ester	F027	4938-72-1

--Isopropyl ester	F027	93-78-7
--Propylene glycol isobutyl ether ester	F027	53466-86-7
--Tripropylene glycol isobutyl ether ester	F027	53535-32-3
4-(2,4,5-Trichlorophenoxy)butyric acid [2,4,5-TB]	F027	93-80-1
2-(2,4,5-Trichlorophenoxy)ethyl hydrogen sulfate [2,4,5-TES]	F027	69633-04-1
1,4',5'-Trichloro-2'-(2,4,5-trichlorophenoxy) methanesulfonanilide [Edolan U]	F027	69462-14-2

PESTICIDES THAT ARE TOXIC HAZARDOUS WASTES

PESTICIDES ON THE "F" LIST [40 CFR 261.33(f)] (with	RCRA #, and	CAS #
Acetone	U002	67-64-1
Acrylonitrile*	U009	107-13-1
Amitrole	U011	61-82-5
Benzene*	U019	71-43-2
Bis(2-ethylhexyl)phthalate	U028	117-81-7
Cacodylic acid	U136	75-60-5
Carbon tetrachloride*	U211	56-23-5
Chloral (hydrate) (chloroacetaldehyde)	U034	302-17-0
Chlordane, technical*	U036	57-74-9
Chlorobenzene*	U037	108-90-7
4-Chloro-m-cresol	U039	59-50-7
Chloroform*	U044	67-66-3
o-Chlorophenol	U048	95-57-8
Creosote	U051	8021-39-4
Cresylic acid (cresols)*	U052	1319-77-3
Cyclohexane	U056	110-82-7
Cyclohexanone	U057	108-94-1
Decachlorooctahydro-1,3,4-metheno-2H-cyclobuta[c,d]-pentalen-2-one (Kepone, chlordecone)	U142	143-50-0
1,2-Dibromo-3-chloropropane (DBCP)	U066	96-12-8
Dibutyl phthalate	U069	84-74-2
S-2,3-(Dichloroallyl diisopropyl-thiocarbamate) (diallate,Avadex)	U062	2303-16-4
o-Dichlorobenzene*	U070	95-50-1
p-Dichlorobenzene*	U072	106-46-7
Dichlorodifluoromethane (Freon 12®)	U075	75-71-8
3,5-Dichloro-N-(1,1-dimethyl-2-propynyl) benzamide (pronamide, Kerb®)	U192	23950-58-5
Dichloro diphenyl dichloroethane (DDD)	U060	72-54-8
Dichloro diphenyl trichloroethane (DDT)	U061	50-29-3
Dichloroethyl ether	U025	1191-17-9
2,4-Dichlorophenoxyacetic, salts and esters (2,4-D)*	U240	94-75-7
1,2-Dichloropropane	U083	8003-19-8
1,3-Dichloropropene (Telone)	U084	542-75-6
Dimethyl phthalate	U102	131-11-3
Epichlorohydrin (1-chloro-2,3-epoxypropane)	U041	106-89-8
Ethyl acetate	U112	141-78-6
Ethyl 4,4'-dichlorobenzilate (chlorobenzilate)	U038	510-15-6

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*Proposed for deletion by TCLP proposal

Ethylene dibromide (EDB)	U067	106-93-4
Ethylene dichloride*	U077	107-06-2
Ethylene oxide	U115	75-21-8
Formaldehyde	U122	50-00-0
Furfural	U125	98-01-1
Hexachlorobenzene*	U127	118-74-1
Hexachlorocyclopentadiene	U130	77-47-4
Hexachloroethane*	U131	67-72-1
Hydrofluoric acid	U134	7664-39-3
Isobutyl alcohol*	U140	78-83-1
Lead acetate	U144	301-04-2
Lindane*	U129	58-89-9
Maleic hydrazide	U148	123-33-1
Mercury	U151	7439-97-6
Methoxychlor*	U247	72-43-5
Methyl alcohol (methanol)	U154	67-56-1
Methyl bromide	U029	74-83-9
Methyl chloride	U045	74-87-3
2,2'-Methylenebis (3,4,6-trichlorophenol) (hexachlorophene) [acute waste per 261.31]	U132	70-30-4
Methylene chloride*	U080	75-09-2
Methyl ethyl ketone*	U159	78-93-3
4-Methyl-2-pentanone (methyl isobutyl ketone)	U161	108-10-1
Naphthalene	U165	91-20-3
Nitrobenzene*	U169	98-95-3
p-Nitrophenol	U170	100-02-7
Pentachloroethane	U184	76-01-7
Pentachloronitrobenzene (PCNB)	U185	82-68-8
Pentachlorophenol* [acute waste per 261.31]	U242	87-86-5
Phenol*	U188	108-95-2
Pyridine*	U196	110-86-1
Resorcinol	U201	108-46-3
Safrole	U203	94-59-7
Selenium disulfide	U205	7488-56-4
Silvex [acute waste per 261.31]	U233	93-72-1
1,1,2,2-Tetrachloroethane*	U209	79-34-5
Tetrachloroethylene*	U210	127-18-4
2,3,4,6-Tetrachlorophenol* [acute waste per 261.31]	U212	
Thiram	U244	137-26-8
Toluene*	U220	108-88-3
1,1,1-Trichloroethane* (methyl chloroform)	U226	71-55-6
Trichloroethylene*	U228	79-01-6
Trichloromonofluoromethane (Freon 11®)	U121	75-69-4
2,4,5-Trichlorophenol* [acute waste per 261.31]	U230	95-95-4
2,4,6-Trichlorophenol* [acute waste per 261.31]	U231	88-06-2

2,4,5-Trichlorophenoxyacetic acid (2,4,5-T)* [acute waste per 261.31]	U232	93-76-5
Warfarin (<0.3%)	U248	81-81-2
Xylene	U239	1330-20-7
Zinc phosphide (<10%)	U249	1314-84-7

83 ACTIVES

CONT/DIS-1

CONTAINER DISPOSAL INSTRUCTIONS

The label of each product must bear container disposal instructions appropriate to the type ot container.

1. Domestic use products must bear one of the following container disposal statements:

Container Type	Statement
Non-aerosol products (bottles, cans, jars)	Do not reuse container (bottle, can, jar). Rinse thoroughly before discarding in trash.
Non-aerosol products (bags)	Do not reuse bag. Discard bag in trash.
Aerosol products	Replace cap and discard containers in trash. Do not incinerate or puncture.

2. All other products must bear container disposal instructions, based on container type, listed below:

Container Type	Statement
Metal containers (non-aerosol)	Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or by other procedures approved by state and local authorities.
Plastic containers	Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or incineration, or, if allowed by state and local authorities, by burning. If burned, stay out of smoke.
Glass containers	Triple rinse (or equivalent). Then dispose of in a sanitary landfill or by other approved state and local procedures.
Fiber drums with liners	Completely empty liner by shaking and tapping sides and bottom to loosen clinging particles. Empty residue into application equipment. Then dispose of liner in a sanitary landfill or by incineration if allowed by state and local authorities. If drum is contaminated and cannot be reused[1], dispose of in the same manner.
Paper and plastic bags	Completely empty bag into application equipment. Then dispose of empty bag in a sanitary landfill or by incineration, or, if allowed by State and local authorities, by burning. If burned, stay out of smoke.
Compressed gas cylinders	Return empty cylinder for reuse (or similar wording)

1/ Manufacturer may replace this phrase with one indicating whether and how fiber drum may be reused.

EPA Compendium of Acceptable Uses

O,O-DIMETHYL S-((4-OXO-1,2,3-BENZOTRIAZIN-3(4H)-YL)-METHYL) PHOSPHORODITHIOATE

TABLE OF CONTENTS

Site Name	Page
TERRESTRIAL FOOD CROPS	3
(Agricultural Crops)	3
Alfalfa	3
Alfalfa-Grass Mixture	3
Almond	4
Apple	5
Apricot	6
Artichokes	8
Barley	9
Beans, Dry	9
Beans, Dry (seed crop)	10
Beans, Snap	10
Birdsfoot Trefoil	10
Blackberry	11
Blueberry	12
Boysenberry	11
Broccoli	13
Brussels Sprouts	13
Cabbage	13
Cauliflower	13
Celery	15
Cherry	15
Citrus Fruits	16
Clover	3
Clover-Grass Mixture	3
Cotton	18
Crabapple	5
Cranberry	21
Cucumber	21
Eggplant	21
Filbert	22
Grapes	22
Loganberry	11
Melons	23
Nectarine	6
Oats	9
Onions, Dry	24
Onions, Green	24
Pasture Grasses	25
Peach	6
Pear	5
Peas, Field	25
Pecan	26
Pepper	26
Pistachio Nuts	27
Plum	27
Potato	28
Prune	27

O,O-DIMETHYL S-((4-OXO-1,2,3-BENZOTRIAZIN-3(4H)-YL)-METHYL) PHOSPHORODITHIOATE

TABLE OF CONTENTS

Site Name	Page
Quince	5
Raspberry	11
Rye	9
Safflower (seed crop)	29
Soybeans	30
Spinach	31
Strawberry	31
Sugarcane	32
Tomato	32
Vetch (seed crop)	35
Walnuts	35
Wheat	9
TERRESTRIAL NON-FOOD CROP	36
(Agricultural Crops)	36
Tobacco	36
(Ornamental Plants and Forest Trees)	36
Ornamental Plants (including shade trees and nursery stock)	36
FORESTRY	39
Forest Trees	39
Pine Plantations	39
Slash Pine (seed orchards)	39
Southern Pine (seed orchards)	39

058001

O,O-DIMETHYL S-((4-OXO-1,2,3-BENZOTRIAZIN-3(4H)-YL)-METHYL) PHOSPHORODITHIOATE*

TYPE PESTICIDE: Insecticide, Acaricide, Molluscicide

FORMULATIONS:
Tech (85%, 94%)
FI (1 lb/gal, 21%, 22%, 25%)
D (2%, 2.5%, 3%, 6%)
G (5%, 7%, 10%)
WP (25%, 50%, 62.5%)
EC (0.25 lb/gal, 0.75 lb/gal, 1 lb/gal, 1.5 lb/gal, 2 lb/gal, 5%, 12.37%)
FlC (2 lb/gal, 3 lb/gal)
SC/L (12.4%)

GENERAL WARNINGS AND LIMITATIONS: All liquid formulations with a concentration greater than 13.5 percent are RESTRICTED USE PESTICIDES. Unprotected persons and beneficial animals should be kept out of the treated area and out of the vicinity where there may be danger of drift. Treated areas should not be re-entered for at least 24 hours unless protective clothing is worn. Do not feed treated crop trash to livestock except where specified. For additional protective information consult your State Cooperative Agricultural Extension Service. For granular formulations, cover or incorporate granules that are spilled during loading or are visible on soil surface in turn areas. Do not use wettable powder water soluble pouches for making highly concentrated mixtures unless they are premixed in nurse tanks with adequate agitation. When using hose-end proportioners do not spray trees or shrubs above 5 feet. The use of undiluted sprays may cause spotting of automobile finishes if prolonged exposure is permitted. Do not spray directly over automobiles. Automobiles touched by spray should be washed immediately. Refer to labeling for appropriate Endangered Species Restrictions.
Protective Clothing: HANDLE THE CONCENTRATE ONLY WHEN WEARING THE FOLLOWING PROTECTIVE CLOTHING AND EQUIPMENT:
Wear a protective suit of one or two pieces that covers all parts of the body except the head, hands and feet. Wear chemical resistant gloves, chemical resistant apron and chemical resistant shoes, shoe coverings or boots. Wear goggles or a face shield. Wear a pesticide respirator approved by the National Institute for Occupational Safety and Health under the provisions of 30 CFR Part II.
FOR LIQUID FORMULATIONS, the following labeling is required:
If handling the concentrate with a closed system, long sleeved shirt and long pants may be substituted for the protective suit and the respirator requirement is waived.
WEAR THE FOLLOWING PROTECTIVE CLOTHING DURING APPLICATION, EQUIPMENT REPAIR, EQUIPMENT CLEANING, DURING EARLY RE-ENTRY TO TREATED AREAS AND DISPOSAL OF THE PESTICIDE:
Wear a protective suit of one or two pieces that cover all parts of the body except the head, hands, and feet. Wear chemical resistant gloves and chemical resistant shoes, shoe coverings or boots.

*Guthion
Azinphos-methyl

GENERAL WARNINGS AND LIMITATIONS (continued)

During application only from a tractor with a completely enclosed cab or aerially with an enclosed cockpit, long sleeve shirt and long pants may be worn in place of the above protective clothing. Chemical resistant gloves must be available in the cab or cockpit and must be worn while exiting. This clothing is inadequate to protect you during equipment repair, equipment cleaning, re-entry, or during pesticide disposal.

Agricultural Crop Tolerances (other than those listed in the text):

5 ppm	Gooseberries
10 ppm	Kiwi fruit
5 ppm	Parsley, leaves
2 ppm	Parsley, roots

Livestock Tolerance:

0.1 ppm	Meat, fat, and meat byproducts of cattle, goats, horses, and sheep

Bee Caution:
Guthion is toxic to bees exposed to direct treatment or residues on crops, and should not be applied when bees are actively visiting the areas.

Definition of Terms:
psi - pounds per square inch
MAI - multiple active ingredient(s)
*Tablespoons/teaspoons actual. A hypothetical quantity computed by multiplying the number (or equivalent number) of tablespoons/teaspoons of product by the concentration of guthion in the formulation.
** Exact computation of actual dosage is not possible because of the lack of weight/volume information on the label. Extrapolation from other formulations reveals that the dosage from this label appears to fall within the range shown by formulations with known weight/volume ratios.

O,O-DIMETHYL S-((4-OXO-1,2,3-BENZOTRIAZIN-3(4H)-YL)-METHYL) PHOSPHORODITHIOATE

TERRESTRIAL FOOD CROPS

(Agricultural Crops)

General Warnings and Limitations: Root crops may be planted 180 days after the last application. All other crops (other than those provided for in CFR 40 180.154) must not be planted within 30 days of last application. Apply wettable powders in sufficient water for thorough coverage by aircraft or ground equipment with the exception of formulations in water soluble packets which are not suited for aircraft applications. Apply emulsifiable concentrate and flowable concentrate formulations in a minimum of 1 gallon per acre by aircraft or ground equipment unless otherwise specified.

	Site and Pest	Dosages and Formulation(s)	Tolerance, Use, Limitations
/23001AA	Alfalfa		2 ppm (alfalfa, clover, grass pasture (green)) 5 ppm (alfalfa hay, clover hay, grass pasture hay) 14 day preharvest/pregrazing interval through 0.375 pound per acre for foliar application. 16 day preharvest/pregrazing interval through 0.5 pound per acre for foliar application. 21 day preharvest/pregrazing interval through 0.75 pound per acre for foliar application. Do not make more than 1 application per cutting through 0.75 pound per acre. Do not make more than 2 applications per cutting through 0.25 pound per acre. Applications to mixed stands of alfalfa-grass or clover-grass are limited to states East of the Mississippi River. Unless otherwise specified apply dosages in a minimum of 1 gallon of water per acre by aircraft and 10 gallons of water per acre by ground equipment.
/28069AA	Alfalfa-Grass Mixture		
/23003AA	Clover		
/28079AA	Clover-Grass Mixture		
IQAMABA	Alfalfa plant bug	0.45-0.75 lb/A (2%, 3% D) or	Foliar application. May be applied by aircraft. Apply when pest first appears and repeat as needed. When making 2 applications per cutting recheck fields 10 to 11 days after the first for proper timing of the second. For alfalfa weevil in heavy growth, apply in a minimum of 5 gal-
IRACAAA	Aphids		
IQAMBDA	Fleahoppers		
IRAFAAA	Leafhoppers		
IQAMARA	Lygus bugs		
ILAAABA	Mites		
IRAEAAA	Spittlebugs		

O,O-DIMETHYL S-((4-OXO-1,2,3-BENZOTRIAZIN-3(4H)-YL)-METHYL) PHOSPHORODITHIOATE

	Site and Pest	Dosages and Formulation(s)	Tolerance, Use, Limitations
	Alfalfa cluster (continued)		
		0.5-0.75 lb/A (25%, 50% WP) (1.5, 2 lb/gal EC) (2, 3 lb/gal FlC)	lons of water per acre by aircraft and in 20 to 25 gallons of water per acre by ground equipment.
NASBWA NASBTA	Alfalfa weevil Egyptian alfalfa weevil	0.25-0.75 lb/A (25%, 50% WP) (1.5, 2 lb/gal EC) (2, 3 lb/gal FlC)	
RACAAA RAFAAA [illegible]	Aphids Leafhoppers Mites	0.25-0.5 lb/A (25%, 50% WP) (1.5, 2 lb/gal EC) (2, 3 lb/gal FlC)	
[illegible]	Grasshoppers	0.5-0.75 lb/A (25%, 50% WP) (1.5, 2 lb/gal EC) (2, 3 lb/gal FlC)	
03001AA	Almond		0.3 ppm (almonds) 10.0 ppm (almond hulls) 60 day preharvest interval through 2.5 pounds per acre for foliar application. Do not make more than 2 applications per fruit year. Do not graze livestock in treated orchards or groves for 21 days after treatment.
TAMABA	Peach twig borer	0.375-0.5 lb/100 gal [max. 500 gal/A] (50% WP) (2 lb/gal EC)	Foliar application. Allow a minimum of 30 days between applications.

O,O-DIMETHYL S-((4-OXO-1,2,3-BENZOTRIAZIN-3(4H)-YL)-METHYL) PHOSPHORODITHIOATE

	Site and Pest	Dosages and Formulation(s)	Tolerance, Use, Limitations
4001AA	Apple		2 ppm 7 day preharvest interval through 2.5 pounds per acre for 6 foliar applications followed by 2 pounds per acre for 2 foliar applications. 15 day preharvest interval through 3.125 pounds per acre for 8 foliar applications. 7 day preharvest interval through 1.5 pounds per acre for 3 foliar applications or 1 pound per acre for 5 foliar applications when applied by aircraft. The sprayable formulations are compatible with dormant and summer oils which may be added to apple and pear sprays in accordance with State Cooperative Agricultural Extension Service recommendations. Do not graze livestock in treated orchards or groves for 21 days after treatment.
4002AA	Crabapple		
4005AA	Pear		
4004AA	Quince		
RACAAA	Aphids	0.75-2.1 lb/A (2.5%, 3%, 6% D) or 0.48-0.96 oz/tree (3% D)	Foliar application. May be applied by aircraft. Apply when pest first appears and repeat at 7 to 10 day intervals as needed. May be formulated with zineb, ferbam, sulfur, or captan.
BMAQA	Apple maggot		
BGAZA	Codling moth		
SBEARA	European apple sawfly		
TBGBOA	Eyespotted bud moth		
RAKBVA	Forbes scale		
TBUAGA	Fruittree leafroller	0.25-0.313 lb/100 gal water [max. 1,000 gal/A] (25%, 50% WP) (2 lb/gal EC)	Foliar applications at 0.25 to 0.313 pound per 100 gallons of water followed by 2 applications at 0.25 pound per 100 gallons of water. Apply at petal fall stage and repeat at 10 to 14 day intervals until control is achieved.
TBCBSA	Green fruitworm		
RAFAAA	Leafhoppers		
RAWAAA	Mealybugs		
LAAABA	Mites		
TBUALA	Orange tortrix		
NASAVA	Plum curculio		
RAKASA	Putnam scale		
TBUAPA	Redbanded leafroller	1-1.5 lb/A (50% WP)	Foliar application. Apply by aircraft. Apply specified dosage in a minimum of 3 gallons of water per acre for the Northwestern United States and in a minimum of 10 gallons of water per acre for other areas. Where aphids and mites are a problem aerial applications may not provide satisfactory control.
RAKBYA	San Jose scale		
QAQAAA	Stink bugs		
QAMATA	Tarnished plant bug		

O,O-DIMETHYL S-((4-OXO-1,2,3-BENZOTRIAZIN-3(4H)-YL)-METHYL) PHOSPHORODITHIOATE

	Site and Pest	Dosages and Formulation(s)	Tolerance, Use, Limitations
	Apple cluster (continued)		
		0.042 oz/gal (1 lb/gal EC) or 2-3 tbls 5% EC/gal (5% EC) or 1 tbls 12.4% SC/L/gal (12.4% SC/L)	Foliar application.
04001AA	(Apple)		
04002AA	(Crabapple)		
04004AA	(Quince)		
OBMAQA	Apple maggot	0.5-1 lb/A (2 lb/gal EC)	ULTRA LOW VOLUME. Foliar application. Use limited to ID, OR, WA, and UT. Apply undiluted by helicopter or fixed wing aircraft using Becomist nozzles with 20 micron sleeves.
TBGAZA	Codling moth		
SBEARA	European apple sawfly		
TBGBOA	Eyespotted bud moth		
TBUAGA	Fruittree leafroller		
TBCBSA	Green fruitworm		
TBUALA	Orange tortrix		
NASAVA	Plum curculio		
TBUAPA	Redbanded leafroller		
05001AA	Apricot		2 ppm 21 day preharvest interval through 2.5 pounds per acre for foliar application. Do not make more than 8 applications per fruiting season. The sprayable formulations are compatible with dormant and summer oils which may be added to peach sprays in accordance with State Cooperative Agricultural Extension Service recommendations. When treating nectarines during bloom period, beekeepers should be warned well in advance to remove hives a safe distance from orchards to be treated. Do not graze livestock in treated orchards or groves for 21 days after treatment.
05003AA	Nectarine		
05004AA	Peach		

O,O-DIMETHYL S-((4-OXO-1,2,3-BENZOTRIAZIN-3(4H)-YL)-METHYL) PHOSPHORODITHIOATE

	Site and Pest	Dosages and Formulation(s)	Tolerance, Use, Limitations
	Apricot cluster (continued)		
RACAAA	Aphids	0.25-0.313 lb/100 gal [max. 800 gal/A] (25%, 50% WP) (2 lb/gal EC) or 0.042 oz/gal (1 lb/gal EC) or 2-3 tbls 5% EC/gal (5% EC) or 1 tbls 12.4% SC/L/gal (12.4% SC/L)	Foliar application. Apply when pest first appears and repeat as needed. For scales, apply when crawlers are present.
RAHAWA	Cottony peach scale		
RAHALA	European fruit lecanium		
RAKBVA	Forbes scale		
TBQALA	Lesser peachtree borer		
LAAABA	Mites		
NASAVA	Plum curculio		
TBUAPA	Redbanded leaf-roller		
RAKBYA	San Jose scale		
QAQAAA	Stink bugs		
QAMATA	Tarnished plant bug		
RAHANA	Terrapin scale		
MOAAAA	Thrips (on nectarines)		
TBUBBA	Variegated leaf-roller		
AKBWA	Walnut scale		
RAKBUA	White peach scale		
ACAAA	Aphids	1.05-2.4 lb/A (3% D) or 0.042 oz/gal (1 lb/gal EC) or 2-3 tbls 5% EC/gal (5% EC) or 1 tbls 12.4% SC/L/gal (12.4% SC/L)	Foliar application. May be applied by aircraft. Apply when pest first appears and repeat as needed. May be formulated with ferbam or sulfur.
LAAABA	Mites		
TBGAQA	Oriental fruit moth		
TAMABA	Peach twig borer		
TBUAPA	Redbanded leaf-roller		
ITBUBBA	Variegated leaf-roller		
ITBQALA	Peachtree borer	0.25-0.313 lb/100 gal (25%, 50% WP) (2 lb/gal EC) or 0.042 oz/gal (1 lb/gal EC) or	Bark application. Apply 2 to 3 sprays to trunk between ground and scaffold limbs, timed with moth flight.

O,O-DIMETHYL S-((4-OXO-1,2,3-BENZOTRIAZIN-3(4H)-YL)-METHYL) PHOSPHORODITHIOATE

	Site and Pest	Dosages and Formulation(s)	Tolerance, Use, Limitations
	Apricot cluster (continued)		
		2-3 tbls 5% EC/gal (5% EC) or 1 tbls 12.4% SC/L/gal (12.4% SC/L)	
ITBGAQA ITAMARA	Oriental fruit moth Peach twig borer	0.25-0.375 lb/100 gal [max. 800/A] (25%, 50% WP) (2 lb/gal EC) or 0.042 oz/gal (1 lb/gal EC) or 2-3 tbls 5% EC/gal (5% EC) or 1 tbls 12.4% SC/L/gal (12.4% SC/L)	Foliar application. Apply the high dosage before mid-season.
/1[illegible]AA	Artichokes		2 ppm 30 day preharvest interval through 1.5 pounds per acre for foliar application. Do not ensile or feed treated forage.
ITBLAAA	Plume moths	1.5 lb/A (25%, 50% WP) (2 lb/gal EC) or 2 tbls 5% EC/gal (5% EC)	Foliar application. Repeat as needed.

0,0-DIMETHYL S-((4-OXO-1,2,3-BENZOTRIAZIN-3(4H)-YL)-METHYL) PHOSPHORODITHIOATE

	Site and Pest	Dosages and Formulation(s)	Tolerance, Use, Limitations
24001AA	Barley		0.2 ppm (barley, oat, rye, wheat grain) 2.0 ppm (barley, oat, rye, wheat straw) 30 day preharvest/pregrazing interval through 0.5 pound per acre for foliar application. Do not make more than 1 application per growing season.
24003AA	Oats		
24005AA	Rye		
24007AA	Wheat		
NAMCMA	Cereal leaf beetle	0.375-0.5 lb/A (25%, 50% WP) (2 lb/gal EC) (2, 3 lb/gal FlC)	Foliar application.
15001AA	Beans, Dry		0.3 ppm 30 day preharvest interval through 0.6 pound per acre for foliar application. Do not make more than 4 applications per growing season. Do not ensile or feed treated forage.
15003AA			
RACAAA	Aphids	0.44-0.6 lb/A (2%, 3% D) or 0.25-0.5 lb/A (25%, 50% WP) (2 lb/gal EC) or 0.042 oz/gal (1 lb/gal EC) or 2-3 tbls 5% EC/gal (5% EC) or 3 tsp 12.4% SC/L/gal (12.4% SC/L)	Foliar application. May be applied by aircraft. Apply when pest first appears and repeat as needed. May be formulated with sulfur.
NAMARA	Bean leaf beetle		
TBCCCA	Green cloverworm		
RAFAAA	Leafhoppers		
MAAAGA	Leafminers		
MAAAEA	Leafrollers		
LAAABA	Mites		
QAQAAA	Stink bugs		
TBCATA	Velvetbean caterpillar		
NAPAFA	Mexican bean beetle	0.5-0.6 lb/A (2%, 3% D) or	
NAMBMA	Spotted cucumber beetle		
NAMBMA	Striped cucumber beetle		
QAMATA	Tarnished plant bug		

O,O-DIMETHYL S-((4-OXO-1,2,3-BENZOTRIAZIN-3(4H)-YL)-METHYL) PHOSPHORODITHIOATE

	Site and Pest	Dosages and Formulation(s)	Tolerance, Use, Limitations
	Beans, Dry (continued)		
	Pest list continued from previous page.		
NAMAEA	Western striped cucumber beetle	0.5 lb/A (25%, 50% WP) (2 lb/gal EC) or 0.042 oz/gal (1 lb/gal EC) or 2-3 tbls 5% EC/gal (5% EC) or 3 tsp 12.4% SC/L/gal (12.4% SC/L)	
15001BA	Beans, Dry (seed crop)		N.F. Do not ensile or feed treated forage.
NAPAFA	Mexican bean beetle	0.5-0.75 lb/A (25%, 50% WP)	Foliar application to seed crop. Repeat as needed.
15003AA	Beans, Snap		2 ppm 7 day preharvest interval through 0.6 pound per acre for foliar application. Do not ensile or feed treated forage.
		Refer to Beans, Dry for pest, use and limitation information.	
23011AA	Birdsfoot Trefoil		2 ppm (birdsfoot trefoil) 5 ppm (birdsfoot trefoil hay) 14 day preharvest/pregrazing interval through 0.375 pound per acre for foliar application. 16 day preharvest/pregrazing interval through 0.5 pound per acre for foliar application. 21 day preharvest/pregrazing interval through 0.75 pound per acre for foliar application.

EPA Compendium of Acceptable Uses

0,0-DIMETHYL S-((4-OXO-1,2,3-BENZOTRIAZIN-3(4H)-YL)-METHYL) PHOSPHORODITHIOATE

	Site and Pest	Dosages and Formulation(s)	Tolerance, Use, Limitations
	Birdsfoot Trefoil (continued)		Do not make more than 1 application per cutting through 0.75 pound per acre.
QAMABA	Alfalfa plant bug	0.5-0.75 lb/A (50% WP)	Use limited to states East of the Mississippi River. Foliar application. Apply when pest first appears and repeat as needed. For alfalfa weevil and Egyptian alfalfa weevil in heavy growth, apply in 20 to 25 gallons of water per acre by ground equipment.
QAMBDA	Fleahoppers		
VABAAA	Grasshoppers		
QAMARA	Lygus bugs		
RAEAAA	Spittlebugs		
NASBWA	Alfalfa weevil	0.375-0.75 lb/A (50% WP)	
NASBTA	Egyptian alfalfa weevil		
RAFAAA	Leafhoppers	0.25-0.5 lb/A (50% WP)	
LAAABA	Mites		
01002AA	Blackberry		2 ppm 14 day preharvest interval through 0.9 pound per acre for foliar application of dust formulations. 14 day preharvest interval through 0.5 pound per acre for foliar application of sprayable formulations. 3 day preharvest interval through 1 pound per acre for application to canes and soil. Do not make more than 2 applications per growing season. Rates above 1 pound per acre should be applied only before fruit set or after the crop is harvested.
01003AA	Boysenberry		
01005AA	Loganberry		
01006AA	Raspberry		
RACAAA	Aphids	0.5-0.9 lb/A (2%, 3% D) or 0.0625 oz/gal (1 lb/gal EC) or 2-3 tbls 5% EC/gal (5% EC)	Foliar application. May be applied by aircraft. Apply when pest first appears and repeat as needed. May be formulated with ferbam or sulfur.
RAFAAA	Leafhoppers		
MAAAGA	Leafminers		
MAAAEA	Leafrollers		
NASDMJ	Obscure root weevil (adults)		
RACAAA	Aphids	0.313-0.51 lb/200 gal/A (25%, 50% WP) (2 lb/gal EC)	